

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

**IN RE: VALSARTAN, LOSARTAN,
and IRBESARTAN PRODUCTS** CIVIL ACTION NUMBER:
LIABILITY LITIGATION 1 : 19-md-02875-RMB-SAK
Daubert Hearing

Mitchell H. Cohen Building & U.S. Courthouse
4th and Cooper Streets
Camden, New Jersey 08101
Tuesday, September 10, 2024
Commencing at 9:35 a.m.

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CHIEF UNITED STATES DISTRICT JUDGE

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15 Loretta Smith, Esquire, Judicial Law Clerk to the Honorable
16 Robert B. Kugler (Ret.)

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4 THE COURTROOM DEPUTY: All rise.

5 CHIEF JUDGE BUMB: Good morning. Good to see you
6 all. Thank you.

7 MR. STANOCH: Good morning, Your Honor.

8 MS. ALLON: Good morning.

9 CHIEF JUDGE BUMB: Okay. I thought about express
10 warranty all night. Woke up this morning thinking about
11 express warranty.

12 (Laughter.)

13 MR. STANOCH: Sorry to hear, Your Honor.

14 CHIEF JUDGE BUMB: Oh, so I took -- I don't want to
15 delay the expert, but I did take a look at the complaint. I
16 think a part of the confusion, and, you know, you all are going
17 to clarify it with the submissions, but I think part of the
18 confusion is, is that the complaint lays out several different
19 warranties that were allegedly breached, express warranties
20 that were allegedly breached, which I think then calls into,
21 well, what is the damages for those. I think. I don't know,
22 that's what you all are going to brief on.

23 So I'm looking at, for example, paragraph 622 of the
24 complaint, 623 and 624. As I read the complaint, those are all
25 separate express warranties.

1 It seems to me the jury would then have to make a
2 finding as to each of those express warranties. And then the
3 question becomes, which is what you folks are going to brief,
4 is, does the law say there are divergent damages depending upon
5 what the warranty being alleged to have been breached is.

6 Does anybody have any questions about what's bugging
7 me and what I need briefing on?

8 MR. HONIK: I think we get it, Judge.

9 MR. STANOCH: Yeah.

10 CHIEF JUDGE BUMB: How about over here?

11 MS. ALLON: Good, Your Honor.

12 MR. OSTFELD: Understood, Your Honor.

13 CHIEF JUDGE BUMB: Yes. Okay.

14 So is Dr. Stiroh here?

15 MS. BRANCATO: She is, Your Honor.

16 CHIEF JUDGE BUMB: Okay. We'll get started.

17 (Witness took the stand.)

18 THE COURTROOM DEPUTY: Raise your right hand.

19 Do you solemnly swear the testimony you're about to
20 give in the case now before this Court will be the truth, the
21 whole truth, and nothing but the truth, so help you God?

22 THE WITNESS: I do.

23 *LAUREN STIROH, Ph.D., called as a witness for the*
24 *Defendants, having been first duly sworn by the Deputy, was*
25 *examined and testified as follows:*

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1 THE COURTROOM DEPUTY: Can you please state and spell
2 your full name for the record.

3 THE WITNESS: Yes. My name is Lauren Stiroh,
4 L-A-U-R-E-N. Stiroh is S-T-I-R-O-H.

5 THE COURTROOM DEPUTY: Thank you.

6 CHIEF JUDGE BUMB: Good morning. How would you like
7 me to address you?

8 THE WITNESS: Dr. Stiroh is fine.

9 CHIEF JUDGE BUMB: Okay. Welcome. Please keep your
10 voice up. If you could bring the microphone close to you. And
11 there's water in the pitcher if you should need it.

12 Okay.

13 MS. BRANCATO: Your Honor, may I proceed?

14 CHIEF JUDGE BUMB: You may.

15 MS. BRANCATO: Thank you.

DEFENDANTS' EVIDENCE

DIRECT EXAMINATION

18 BY MS. BRANCATO:

19 Q. Good morning, Dr. Stiroh.

20 A. Good morning.

21 Q. Can you please introduce yourself to the Court when you're
22 ready.

23 A. Yes. I am Dr. Lauren Stiroh. I'm an economist.

24 Q. And, Dr. Stiroh, did you prepare any slides today to
25 assist with your testimony?

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1 A. I did, yes.

2 MS. BRANCATO: Your Honor, may I approach?

3 CHIEF JUDGE BUMB: You may.

4 MS. BRANCATO: I tried to do this electronically, but
5 it didn't work out, so I thought paper might be most efficient
6 at this point.

7 BY MS. BRANCATO:

8 Q. Dr. Stiroh, these are the slides you prepared to testify
9 or aid your testimony today?

10 A. They are, yes.

11 Q. Let's look at slide 2 titled: Education and Experience.

12 Can you start by telling us how long you've been an economist?

13 A. Yes. I have been an economist for about 30 years.

14 Q. And can you please tell the Court about your educational
15 background?

16 A. Yes. I have a BA in economics from the University of
17 Western Ontario; a master's in economics from the University of
18 British Columbia; and a Ph.D. in economics from Harvard
19 University.

20 Q. Where do you currently work?

21 A. I work in White Plains, New York. My office is there, and
22 the company I work for is called NERA Economic Consulting.

23 Q. What's your title at NERA?

24 A. It is Senior Managing Director.

25 Q. And how long have you been with NERA now?

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1 A. Almost 30 years. I started there after finishing my Ph.D.
2 in 1996.

3 Q. Over the course of your 30-, 35-year career, have you ever
4 served as an expert witness in a lawsuit?

5 A. I have.

6 Q. In approximately how many cases?

7 A. I think it is probably close to a hundred by now.

8 Q. And of those 100, how many would you say approximately
9 were as a damages expert?

10 A. I think probably half of them. I haven't counted
11 specifically, but I think about half of them may be damages
12 cases.

13 Q. Let's look at Slide No. 3.

14 Dr. Stiroh, can you tell us what your assignment was
15 in this case?

16 A. Yes. I was asked to evaluate Dr. Conti's opinions
17 specifically with respect to her opinion that the drugs were
18 worthless and that also to evaluate her damages calculations
19 and opinions.

20 Q. At a high level, what is your understanding of Dr. Conti's
21 opinion regarding damages?

22 A. At a high level, her opinion is that the drugs at issue
23 were worthless, and her damage calculation intends to sum up
24 all of the payments that were made for the drugs from 2012
25 through the time of the recall.

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1 Q. And in responding or evaluating Dr. Conti's damages
2 opinion, did you do your own calculation of the TPPs' damages
3 in this case?

4 A. I did not.

5 Q. Why did you not do that calculation?

6 A. It was not part of my assignment. I was asked to evaluate
7 Dr. Conti's calculations, methodologies and opinions, and
8 that's what I did.

9 Q. Dr. Stiroh, we're going to talk a lot today about a
10 counterfactual world or a but-for world.

11 Can you just tell us what that means at the outset?

12 A. Yes.

13 To an economist, it's the world that didn't happen.
14 It is a way to evaluate economic impact from some sort of
15 conduct that's alleged to be improper. The but-for world is
16 what does the world look like if that conduct had never
17 occurred, what would economic outcomes have been, what would
18 economic relationships have been, but essentially a fully
19 constructed world that looks like the current world except for
20 the conduct at issue.

21 Q. Does Dr. Conti construct a but-for or counterfactual world
22 to arrive at her opinion?

23 A. She does.

24 Q. And what is that but-for, counterfactual world she
25 constructs?

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1 A. Her counterfactual world is to take away the defendants'
2 supply of valsartan-containing drugs. So the difference
3 between the actual world and the but-for world is there's no
4 supply of defendant manufacturer VCDs.

5 Q. And in the real world, there was supply up until the
6 recall; is that right?

7 A. Yes.

8 Q. Let's turn to slide 4, please.

9 Dr. Stiroh, can you please tell us about your first
10 opinion?

11 A. Yes.

12 So with respect to Dr. Conti's opinion that the drugs
13 were worthless, in my view that's not supported by economic
14 reasoning. It's that she has a world where she has taken away
15 supply but then not considered what economic factors come out
16 of that, how do economic relationships change, and what would
17 happen in a world where we took away supply from the defendant
18 manufacturers.

19 Q. And can you please tell us what your second opinion is?

20 A. My second opinion is that one of the things that happens
21 in that but-for world, if we were to just take away the supply
22 from the defendant manufacturers, the people that took the
23 drugs got a benefit from taking the drugs. They're not
24 worthless. They were -- they had some therapeutic value. So
25 in the but-for world that she constructs, we have people

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1 getting a therapeutic value from the drug without having ever
2 paid for it for all of the years up until the recall. And what
3 that does is it puts more money back for the TPPs that are at
4 issue, I understand from this hearing today, and makes them
5 better off than they would have been had the drugs, the
6 adulterated drugs never been in the system, if the adulteration
7 had never occurred in the first place.

8 CHIEF JUDGE BUMB: Can you try that again? Can you
9 say what you just said again?

10 THE WITNESS: Yes.

11 So the -- let me just reorient myself.

12 So in the but-for world that Dr. Conti has, we take
13 away the supply from the defendant manufacturers. In my view,
14 it's not a properly constructed but-for world because the end
15 result is not supported by economics. The end results that we
16 have there is from 2012 through 2018, consumers were taking
17 valsartan, receiving the therapeutic benefit. But if we give
18 them and the TPPs back all of the money they ever paid, the
19 TPPs end up in a situation where their covered patients
20 received a therapeutic value and nobody paid for it. So they
21 get back all of the money, they still get a value, and that is
22 not an economic outcome. It's not a proper measure of economic
23 loss.

24 BY MS. BRANCATO:

25 Q. In that situation where the TPPs get back all of the

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1 value, would that be a windfall?

2 A. That is a windfall. It makes them better off than they
3 would have been had the contaminants never been added to the
4 product.

5 Q. Dr. Stiroh, in prepping for today, did you review the
6 TPPs' *Daubert* motion to exclude part of your damages opinion?

7 A. I did.

8 Q. And do you understand that the *Daubert* motion is the
9 subject of today's hearing?

10 A. I do.

11 Q. Which of your opinions do you understand the TPPs to be
12 challenging today?

13 A. I understand they are challenging the aspect of the second
14 opinion where I'm considering the damage methodology, testing
15 the reasonableness, and I consider the price of alternative
16 drugs in looking at the reasonableness of that outcome.

17 I don't understand them to be challenging my opinions
18 that the drugs were not worthless.

19 Q. Let's turn to slide 5, please, and focus a little bit more
20 on the second opinion.

21 What's the first -- sorry, the printout is a little
22 unclear, but it would have been clear on the screen. What's
23 the first ground for your second opinion that the TPPs -- or
24 that Dr. Conti hasn't demonstrated that the TPPs suffered any
25 economic loss?

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1 A. Yes. It's faded out a little bit on the printout so you
2 can't see what it is that I'm about to say, but that there is
3 value. There is value in the valsartan-containing drugs. They
4 have a risk that was not disclosed at the time that they were
5 taken. But from the TPPs' perspective, there is value in those
6 drugs. And so that isn't something -- that is not considered.
7 It's not incorporated into Dr. Conti's opinion.

8 Q. And what exactly is the value that the TPPs receive from
9 the VCDs?

10 A. So the TPPs' role is, essentially, it's a business role.
11 They have a business relationship in the supply chain. They
12 don't of course take the drugs themselves. They facilitate
13 payments for the drugs. They facilitated those payments. The
14 drugs were manufactured. Prescriptions were written by
15 doctors. When the prescription was filled, the amount that is
16 paid, the agreed upon amount is covered by TPPs. So that role
17 was still fulfilled in the supply chain.

18 Q. And what is the second ground for your second opinion?

19 A. It is related to what we said before about in Dr. Conti's
20 world there's a windfall. If we were to take away the
21 defendant manufacturers' supply of valsartan-containing drugs,
22 the TPPs would not have been better off. Two things could
23 happen. We take away that supply and either the patients don't
24 take something to replace it, if it did nothing for them, if
25 there was no value and they took nothing to replace it, then

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1 those payments never occur. But if they have to take something
2 to replace it, the role of the TPP is to cover what the
3 prescription is that the doctor writes.

4 So when there is value in managing hypertension and
5 some drug is going to be taken, from the TPPs' perspective, as
6 an economic matter, they don't get better off if we take away
7 the supply. Their payments would be at best the same, at worst
8 higher.

9 Q. And just to be clear, do you understand the TPPs to be
10 challenging both of these bases for your second opinion or one
11 or another?

12 A. I understand that they are not challenging my opinion
13 regarding worthlessness; that they are not challenging that the
14 drugs had some value. I understand them to be challenging when
15 I look at the prices of alternative drugs in evaluating the
16 reasonableness of the outcomes.

17 Q. Let's talk about the methodology you used to reach your
18 conclusion that the TPPs would not be better off due to paying
19 for more expensive alternatives.

20 Let's look at slide 6, please.

21 Dr. Stiroh, can you please explain the methodology
22 you used to reach the conclusion that the TPPs would have paid
23 for more expensive alternatives in the but-for world?

24 A. Yes.

25 So first, I consider the ways in which a third-party

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1 payor, a TPP, could be harmed in this situation. I look at --
2 I consider what their economic outcomes are and how the
3 economic outcomes would be different but for the wrongful
4 conduct, so but for the contaminated products, and I consider
5 is there an economic difference to say that there is an
6 economic loss.

7 So the first step is considering the ways in which a
8 third-party payor could be injured and then evaluating did
9 Dr. Conti look at whether there was injury that accrues to the
10 third-party payor.

11 Q. Let's talk about each of these steps one by one just so
12 we're clear. Starting with the first step, and we can go to
13 slide 8, please.

14 Dr. Stiroh, can you please explain what we're seeing
15 on the slide?

16 A. Sure.

17 So this is one of the references in my report that I
18 point to that an approach to economic damages is to construct a
19 but-for world and compare the but-for world to the actual
20 world, and differences in economic outcomes are the measure of
21 economic loss. And it is an approach to evaluate from an
22 economic point of view what's the money that comes from the
23 conduct at issue.

24 Q. Is this analysis you're doing also sometimes called a
25 "make-whole" approach?

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1 A. Yes. It comes by different names. One is "make whole,"
2 and that is make the plaintiff whole in money terms for the
3 harm that was done to them. Another is compensatory damages,
4 what compensates the plaintiff for the money damages that they
5 incurred, and but-for damages. You see all of those phrases
6 generally to mean the same approach.

7 Q. Let's look at slide 9, please.

8 Dr. Stiroh, focusing on the TPPs specifically, how
9 can they be damaged?

10 A. So, as I said, the TPPs' role, they're a business entity,
11 and they conduct business and earn profits through the
12 business.

13 The way a business gets harmed is a reduction in
14 profits compared to what they otherwise would have earned
15 absent some wrongdoing. And so on this slide it's showing the
16 distinction between the ways in which somebody that took a
17 contaminated product can be harmed, which would include in it
18 some sort of medical implication, and the way a business could
19 be harmed. And that has to do with differences in economic
20 outcomes, because that is the -- the measure of benefit to a
21 business is additional profit. A measure of harm is reduced
22 profit.

23 Q. Can we turn to slide 10, please.

24 Dr. Stiroh, 10 and 11 are an attempt to illustrate
25 what the but-for world might look like in simpler terms. Let's

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1 start with slide 10. Can you describe what we see on slide 10?

2 A. Yes.

3 So this is an illustration of the way a damage
4 calculation typically proceeds. You look at -- for a business,
5 you look at what are the costs or, alternatively, what are the
6 profits that they earn in the actual world and then compare
7 that to the but-for world and consider what their economic
8 outcomes are in the but-for world. And if there is a
9 difference, if they would have been better off in the but-for
10 world, that measure of difference is the economic loss damages.

11 Q. And turning to slide 11.

12 CHIEF JUDGE BUMB: Have you ever done any such
13 analysis in a case similar to this, in a pharmaceutical case
14 similar to this where the allegation was that they were
15 contaminated drugs?

16 THE WITNESS: I have not done this analysis for
17 contaminated drugs. I've done economic loss damages, and those
18 types of considerations are similar. So it is thinking about
19 the business entity of a third-party payor separate from what's
20 the impact to a consumer that took the product.

21 CHIEF JUDGE BUMB: And have you done any analysis in
22 any cases where the allegation is, is that warranties were made
23 that turned out to not be true?

24 THE WITNESS: Yes. I have worked on other contract
25 cases and warranty cases where the difference is what is the

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1 value received versus the value bargained for. And as I
2 described in my report, it's the similar type of analysis of
3 what's the diminution of value, by how much is the value
4 reduced by the conduct. That would go to the worthlessness
5 theory that we were talking about earlier. They're not
6 worthless. There's some value there. And what was never
7 measured was what is the amount by which the value has come
8 down.

9 CHIEF JUDGE BUMB: Have you ever done an analysis in
10 a case where the allegation is, is that there were warranties
11 made and the injured party took the position and/or prevailed
12 in the position that the product was worthless?

13 THE WITNESS: I have not been in a matter where there
14 was a position that the product was worthless. I have given
15 testimony in a matter where there were representations of the
16 mileage an automobile would get and the actual mileage was
17 different from the mileage. The allegation I don't think
18 included worthlessness in there. But the same consideration of
19 what was known at the time that the price was struck and what
20 would have happened had more information been available at that
21 time.

22 CHIEF JUDGE BUMB: What case was that?

23 THE WITNESS: I expect you want it by the caption.
24 The company that I worked for was Ford Automobile. And I would
25 have to look that up for you. Oh, I think it's in my CV.

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1 CHIEF JUDGE BUMB: Was it a recent case?

2 THE WITNESS: It's a case in Canada.

3 CHIEF JUDGE BUMB: So it wouldn't have applied
4 American law?

5 THE WITNESS: It would not have applied to American
6 law.

7 CHIEF JUDGE BUMB: U.S. law.

8 THE WITNESS: It's the same type of consideration.

9 CHIEF JUDGE BUMB: Okay.

10 BY MS. BRANCATO:

11 Q. Dr. Stiroh, looking at slide 11, can you tell us what we
12 see on this slide and how that's different from what we saw in
13 slide 10?

14 A. Yes. So slide 10 shows the typical case of economic loss
15 where a plaintiff is economically worse off than they would
16 have been absent the wrongdoing. And here we have a
17 complication that in the actual world, they bargained for
18 valsartan-containing drugs. They had the value of those drugs.
19 Had that supply been taken away, then economics tells you price
20 would go up; costs of alternatives are higher. They are not --
21 the TPPs would not be better off in an economic sense if we
22 took away the supply for valsartan-containing drugs. So there
23 is not a money damages amount. If we just take that away --
24 sorry, take away the supply and give back all the money, we've
25 given a windfall. We've made the defendant better off.

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1 And my understanding of compensatory damages is you
2 put them back in a position they would have been had the
3 wrongdoing never occurred, not put them in a position that
4 makes them better off for the wrongdoing having had occurred.

5 CHIEF JUDGE BUMB: So you're familiar with all of
6 the -- I just want to know if you've worked on any such types
7 of these cases.

8 So there have been many cases over the years where
9 there is, let's say, a recall of lettuce for -- what is it?
10 Salmonella or whatever.

11 THE WITNESS: Yeah.

12 CHIEF JUDGE BUMB: Have you ever worked on those
13 kinds of cases?

14 THE WITNESS: I have not. I am, you know, familiar
15 with the situation and can talk about the economics involved.
16 The recent recall, I think of deli meat. And I think the
17 comparable situation is what if you ate your sandwich already
18 and you didn't get sick? You had your sandwich, you didn't
19 have to buy a second lunch. The economic damages would be did
20 you have to buy a second lunch. If you took what was in your
21 refrigerator and you threw it away and now you have to go
22 grocery shopping again, that is the economic impact; what are
23 the additional costs.

24 CHIEF JUDGE BUMB: That's the same analysis you're
25 doing here?

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1 THE WITNESS: Yes, the same analysis that I'm doing
2 here.

3 CHIEF JUDGE BUMB: Okay.

4 BY MS. BRANCATO:

5 Q. Dr. Stiroh, just to be clear, is slide 11 what you think
6 is happening in this case in your opinion?

7 A. Under Dr. Conti's theory of damages, yes, there is a
8 windfall.

9 Q. Dr. Stiroh, we're going to talk more about the methodology
10 here. But I want to ask you: Could there be a world where the
11 TPPs do have damages under your methodology in a different set
12 of facts?

13 A. Yes. Similar to what I just explained with the ham
14 sandwich, that at the time of the recall, if there's patients
15 that have valsartan in their cabinets, they just went and got a
16 90-day supply, now they throw it away and get something else,
17 if the TPPs had to cover that additional prescription and they
18 wouldn't have had to cover that, if there had never been any
19 contaminants being added, that's that additional costs, what
20 are the additional costs that get imposed on them because of
21 the recall.

22 So if there were patients that didn't fill the end of
23 their prescription and instead went out and got something new
24 and the TPP had to cover that, that would be the type of
25 economic damages where there is a difference between the

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1 economic position they're in and the economic position they
2 would have been in but for the wrongdoing.

3 Q. That's not the analysis that Dr. Conti did; is that right?

4 A. That is not the analysis, correct.

5 Q. Does Dr. Conti's approach to damages allow for any
6 alternative possibilities where the TPPs could have had
7 damages?

8 A. In my view, she only calculates one. And it is the giving
9 back all of the amount of money that was ever spent on
10 valsartan-containing drugs and doesn't look, for TPPs, at what
11 is the impact on them and is there an avenue where their costs
12 were higher where they did suffer a financial penalty because
13 of the contamination.

14 CHIEF JUDGE BUMB: And so you're saying that the TPPs
15 get a windfall under her analysis?

16 THE WITNESS: That's correct, yes.

17 BY MS. BRANCATO:

18 Q. Dr. Stiroh, let's look at slide 12, please.

19 After you analyzed the type of harm or the economic
20 loss that the TPPs could suffer, can you please remind us what
21 the next step of your methodology is?

22 A. Yes.

23 To do that, you have to think about what is the
24 but-for world, what happens in the actual world, what happens
25 in the but-for world.

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1 So the example we just talked about, if in the actual
2 world they had to pay twice for prescriptions, in the but-for
3 world they would not, that's the economic damages.

4 In Dr. Conti's world, the but-for world she takes
5 away the supply of VCDs from the defendant manufacturers and
6 then does not consider what happens logically next after doing
7 that. But the construction of the but-for world is you make a
8 world that's economically rational.

9 Q. Turn to slide 13, please.

10 Dr. Stiroh, in your experience, is considering a
11 but-for or a counterfactual world relevant only in antitrust
12 cases?

13 A. It is not. This slide, the excerpt that you see on slide
14 13, that's from the same reference manual that I showed the
15 initial quote about what the but-for world is, and this one is
16 an application to fraud specifically, where it is the same --
17 from an economic perspective, it is the same type of analysis
18 of but for the fraud what happens. And the example given is
19 considering, well, but for fraud what would the parties have
20 done? In this example, would they have purchased a different
21 property, and then that difference tells you what the economic
22 impact is.

23 But the reason for this slide is to just demonstrate
24 that that type of analysis is not specific to one type of law.
25 It is common in economics for different types of wrongdoing

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1 where we would try to measure what an economic loss is or
2 compensatory damages or make-whole damages.

3 CHIEF JUDGE BUMB: And to be clear, you're only
4 opining on compensatory damages. You're not opining on
5 punitive damages or fraud induced penalties; you're limiting
6 your analysis to compensatory?

7 THE WITNESS: A hundred percent. The economics tells
8 you compensatory damages, and I think that an analysis where it
9 is intended to be punitive takes us away from economics. The
10 economics tells you what is the economic impact on the
11 plaintiffs.

12 BY MS. BRANCATO:

13 Q. Let's turn to slide 14, please, Dr. Stiroh. I want to ask
14 you a few questions about Dr. Conti's but-for or counterfactual
15 world.

16 Can you tell us what we're looking at on slide 14?

17 A. Yes. The two figures that are labeled Figure 1 and
18 Figure 2, these come from Dr. Conti's report. And, you know,
19 we've mentioned them a few times today and I think yesterday as
20 well.

21 So the figure on the left-hand side is a typical
22 supply and demand chart that you see in economics textbooks.
23 And Figure 2 is Dr. Conti's but-for world that I'm evaluating,
24 where she has taken away the supply but left a demand curve,
25 left the demand for the products at issue.

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1 Q. And is that the but-for, counterfactual world you heard
2 Dr. -- or Professor Conti testifying about yesterday?

3 A. Yes.

4 Q. How does Dr. Conti calculate damages in this but-for world
5 where there's no supply?

6 A. As she said yesterday, she adds up the amounts that were
7 spent on the valsartan-containing drugs manufactured by
8 defendants.

9 Q. Did Dr. Conti consider any alternative actions that the
10 TPPs may have taken in the but-for or counterfactual world?

11 A. She did not. That's part of my critique of the analysis
12 where I say that is not an economic outcome. That amount of
13 money, if you just take it away, you end up with a windfall.
14 If the patients that took the valsartan-containing drugs had
15 their hypertension managed, the TPPs fulfilled their
16 obligations of covering the prescriptions that were written by
17 doctors. And if we take away that supply, we haven't
18 considered what else happens, and it matters to economic
19 damages.

20 The example I gave earlier, you could imagine two
21 very different outcomes. One, the drug is actually worthless
22 and doesn't need to be replaced, or, two, the drug has some
23 therapeutic value and needs to be replaced, and that gives you
24 the chain of reasoning to what's the economic position of the
25 third-party payors. In this but-for world, if we were to take

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1 away supply because it had value, it has to be replaced.

2 CHIEF JUDGE BUMB: So were you in the courtroom
3 yesterday?

4 THE WITNESS: I was, yes.

5 CHIEF JUDGE BUMB: Okay. So I gave a hypothetical
6 yesterday. If you could just opine on this.

7 What if it turned out, and of course these aren't the
8 facts, but what if it turned out that over the course of these
9 years the defendants were supplying placebos, turned out they
10 just -- they were worthless, tell me about your analysis there.

11 THE WITNESS: I think that what happens there, but
12 it's not what actually did happen.

13 CHIEF JUDGE BUMB: No, I understand.

14 THE WITNESS: So if they are actually worthless, and
15 the doctor agrees this is worthless, this doesn't do anything,
16 I should never have prescribed it, in that situation where they
17 are worthless, then there's no windfall. There's a windfall
18 when you've got a benefit and you never had to pay for it.

19 CHIEF JUDGE BUMB: Okay. What's the windfall?

20 THE WITNESS: The windfall is it's the -- if you give
21 them back the money --

22 CHIEF JUDGE BUMB: Oh, because they didn't have to
23 go -- well, no. I interrupted you.

24 THE WITNESS: No; you're right. If they didn't have
25 to pay for something else -- let me start again with that.

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1 The windfall is that the people that took the drug
2 and the people that covered the prescriptions for the drug --

3 CHIEF JUDGE BUMB: For the placebo.

4 THE WITNESS: For the -- well, there's a windfall in
5 the real world where the drug has a benefit.

6 CHIEF JUDGE BUMB: No. Talk to me about my
7 hypothetical about the placebo.

8 THE WITNESS: Yes. Sorry.

9 CHIEF JUDGE BUMB: Yeah.

10 THE WITNESS: When it's a placebo, when it really is
11 literally zero?

12 CHIEF JUDGE BUMB: Truly.

13 THE WITNESS: There's no windfall because there
14 wasn't a benefit. There wasn't a benefit of taking the
15 product.

16 CHIEF JUDGE BUMB: There's no windfall because there
17 wasn't a benefit.

18 THE WITNESS: It's when there's a benefit so that the
19 patients took it, they received a medical benefit for the six
20 years up to the recall and now they get all of the money back
21 as well. They got a benefit that they didn't pay for to get
22 their money back. That's the windfall.

23 If there was no benefit, there's no windfall.

24 CHIEF JUDGE BUMB: What about the argument that,
25 well, you know, we didn't know it was a placebo, but had we

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1 known, you would have gone, you, the TPPs, would have had to
2 have gone out and buy more, the real deal? What about that
3 analysis?

4 THE WITNESS: We didn't know it was a placebo? So
5 that if there was no value to it at all?

6 CHIEF JUDGE BUMB: But had they known earlier, they
7 would have had -- they would have gone out and bought -- paid
8 for a legitimate drug.

9 THE WITNESS: Yes. So then --

10 CHIEF JUDGE BUMB: What's your analysis? What's your
11 analysis say?

12 THE WITNESS: In that case then, they would have paid
13 for the alternative drugs but gotten an additional benefit from
14 the working product as well. Does that make sense? So there's
15 the money payment and the therapeutic value, and I'm comparing
16 the actual world to the but-for world.

17 So I think in your scenario, no value to the actual
18 drug. But-for world you paid for something else but you also
19 get a benefit. That's a difference between where you would
20 have been and where you are, and that it would be the value of
21 the benefit is what is missing from the current world.

22 CHIEF JUDGE BUMB: Okay.

23 BY MS. BRANCATO:

24 Q. And in that situation, there would be damages?

25 A. Yes.

1 Q. Dr. Stiroh, in rebutting Dr. Conti's opinion, what but-for
2 world or counterfactual world did you consider?

3 A. Well, for purposes of today's testimony, I considered the
4 one that she puts forward where we take away the supply of
5 valsartan-containing drugs from the defendant manufacturers.

6 Q. Let's look at slide 15, please.

7 In evaluating Dr. Conti's but-for or counterfactual
8 world, what evidence did you consider?

9 A. I looked at a variety of things that were in the record.
10 I looked to see, you know, first what happens if we take away
11 that supply. And so I looked at the testimony from the TPPs.
12 I looked at testimony from the covered patients. As an
13 economist, I looked at economic literature. I looked at the
14 various datasets that were produced in this matter and
15 considered the reasonableness of her opinion.

16 Q. After considering all this evidence, did you find
17 Dr. Conti's methodology and opinion to be economically
18 reasonable?

19 A. I did not.

20 Q. And why not?

21 A. Well, first, there is testimony that the drugs had value;
22 that they were not worthless; that they provided a benefit to
23 the people that took them.

24 CHIEF JUDGE BUMB: And your analysis would have
25 changed if -- if -- going back to my placebo example, if the

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1 testimony is that they were worthless?

2 THE WITNESS: Yes. I would say the outcomes would
3 have changed. So the results of my analysis would have
4 changed, but the approach of considering --

5 CHIEF JUDGE BUMB: Stay the same.

6 THE WITNESS: Yeah, the approach stays the same, and
7 the outcome would be different.

8 CHIEF JUDGE BUMB: Yes. Understood.

9 BY MS. BRANCATO:

10 Q. Dr. Stiroh, let's look at slide 16, please.

11 Is this the TPP testimony you've been mentioning?

12 A. Yes. This is an excerpt from the deposition of one of the
13 representatives from Emblem, and that's the name of one of the
14 third-party payors in this case. And what's being highlighted
15 is just where she is acknowledging that they would have covered
16 some other drug to treat hypertension.

17 Q. And why is the fact that they would have covered something
18 else relevant to your methodology?

19 A. It tells me that there's value to covering hypertension
20 for patients, obviously something we know anyway, but that it
21 is relevant for this case that in considering what happens when
22 you take away the supply and now I'm going to look at the
23 position of the third-party payor, what position are they in.
24 I'm looking at the evidence. It's not saying, well, these
25 drugs are placebos, we never would have covered anything at

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1 all. They're saying they would have covered something else.

2 Q. Turn to slide 17, please. And we're up to step three of
3 the methodology.

4 Can you summarize for us what the analysis in this
5 step entails?

6 A. Yes.

7 This is one of the things that I'm looking at to
8 evaluate the reasonableness of the opinions, what happens if
9 you take away supply and something else gets covered. Through
10 that chain of reasoning, which is the chain of reasoning in
11 Dr. Conti's but-for world, the TPPs aren't better off. The
12 prices of alternatives were higher, or if we take away supply,
13 then the price of the remaining manufacturers of
14 valsartan-containing drugs that weren't recalled, that price
15 would be expected to go up.

16 So the chain of events that lead you to the but-for
17 world in Dr. Conti's damage assessment doesn't tell you an
18 economic harm to TPPs. They would not have been economically
19 better off if we were to take away that supply if the
20 wrongdoing had never happened through that avenue.

21 Q. Let's look at slide 18 briefly because you just summarized
22 this.

23 I just want to be clear, number one is inflated
24 prices for VCDs from other manufacturers whose drugs weren't
25 recalled. That's one of the bases you were just talking to

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1 Judge Bumb about; is that right?

2 A. Yes, that's right. They're two different things that I'm
3 considering. One is just the valsartan if they had switched to
4 a different valsartan that's not recalled, and another is if
5 they switched to a different product altogether. I considered
6 both of those. And both of them would be higher prices,
7 leaving the TPP no better off if the supply had been taken
8 away.

9 Q. Let's start with the fact that prices for VCDs that
10 weren't recalled would increase.

11 Looking at slide 19, can you tell us what you see on
12 this slide?

13 A. Yes. This is an example of some of the economic
14 literature that I reviewed. It's probably generally familiar
15 to you or expected anyway. There are lots of studies that show
16 what's the impact of generic competition. And so the authors
17 of this study are showing that the more generic competitors
18 there are, generally the more and more the price comes down
19 relative to the brand.

20 So one of the things I start with was just looking at
21 economic literature generally and then I see what's the supply
22 to valsartan as well.

23 Q. Looking at slide 20, can you tell us where this chart is
24 from and what's it showing?

25 A. Yes. Where you see it says Figure 1, that's -- it's drawn

1 right from my report. It was Figure 1 in my report. So
2 just -- it's the outcome of what I just explained. I looked at
3 the economic literature, what did those authors do for drugs
4 generally, and then verifying that that same relationship holds
5 for valsartan. And so it is showing you the discount off the
6 brand; and when there are few generic manufacturers, it's a
7 pretty small discount. As more and more enter, there comes a
8 bigger and bigger discount off the brand. And so that's
9 verifying that same relationship in economic literature holds
10 for these drugs.

11 Q. So if the defendant manufacturers had not entered the
12 market in the but-for world or the counterfactual world, what
13 would have been the impact on the price of VCDs?

14 A. My expectation as an economist, we have fewer generic
15 manufacturers competing, the drug prices wouldn't have fallen
16 as much as they did in the actual world.

17 Q. Let's look at slide 21, please.

18 Dr. Stiroh, can you explain what we're looking at on
19 this slide?

20 A. Yes. This is another one of the analyses that I did.
21 It's essentially a lot in the same vein; that the black line
22 that you see starting up at 40 cents and dropping down, that's
23 the average price of the valsartan-containing drugs. And I'm
24 just mapping that on to how much of the supply comes from the
25 defendant manufacturers. And I'm considering that just, you

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1 know, was it a trivial amount of supply? We're taking it away.
2 You wouldn't expect it to have much of an economic impact.
3 It's not a trivial change. It is a pretty significant change.
4 The defendants account for about 88 percent of the
5 valsartan-containing drugs by 2018. So taking away that supply
6 would be expected, as an economic matter, to have a pretty big
7 impact.

8 Q. And when you say pretty big impact, you mean increase the
9 price of other VCDs?

10 A. That would be my expectation, yes.

11 Q. If defendants had not sold VCDs in the but-for,
12 counterfactual world and the price of VCDs from other
13 manufacturers had increased, what would have been the financial
14 impact on the TPPs?

15 A. Well, as we talked about before, that makes them better
16 off -- I mean worse off in a counterfactual world where there
17 is no supply from defendants. They would have higher costs in
18 that world than they actually have had.

19 Q. Did Dr. Conti consider how much the TPPs would have paid
20 for VCDs from other nondefendant manufacturers?

21 A. She does not. She basically just gives back the money
22 that they actually spent without thinking, you know, what
23 happens now, what happens now that we've taken away that
24 supply.

25 Q. I want to talk now about the prices of other hypertension

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1 drugs. Let's look at slide 22, please.

2 Dr. Stiroh, based on your analysis, what would have
3 happened if the TPPs' members did not take a VCD in the but-for
4 world?

5 A. So this, what's being shown on slide 22 is essentially,
6 it's an illustration of the one of the things that I did to
7 look at exactly that question. And here instead of, you know,
8 having a theory of what would have happened, I looked at what
9 did happen. So there was one of the TPPs produced data that
10 showed for patients what they were paying to cover VCDs prior
11 to the recall and then for the same patient, what they paid for
12 that patient and the product that they switched to. And so I
13 calculated what the differences were. And I'm seeing that
14 almost 80 percent switched to another ARB product, so a similar
15 class of products to manage hypertension. That's what's being
16 reflected on page 22 here.

17 But the analysis generally, I'm looking at the data
18 to see what did they spend their money on, how much did they
19 spend for the same set of patients.

20 Q. And just to be clear, the data you're looking at from
21 slide 22, this is from one of the TPPs; is that right?

22 A. It is. The TPP is called SummaCare, and it is rolled up
23 into MSP.

24 Q. Let's look at slide 23, please.

25 And talk a little bit about the prices of these other

1 ARBs.

2 Dr. Stiroh, what did your analysis show about the
3 price of the other ARBs that the TPPs' members would have
4 switched to?

5 A. Generally, that they are higher; that they -- this is part
6 of my overall analysis considering if they didn't take the
7 product at issue, what would they take. So I've seen in the
8 data most of them switched to a different ARB, and I look at
9 the prices of the other ARBs. And for most of the ones that
10 the patients switched to, the prices were higher.

11 CHIEF JUDGE BUMB: Can I say the following, because
12 I'm trying to absorb this and see if you -- I think -- can you
13 just respond to this? Because it seems to me that what is
14 integrated into your analysis is the fact that the product had
15 some value.

16 (Witness nodding.)

17 CHIEF JUDGE BUMB: It may not have been as it was
18 represented but it had some value.

19 (Witness nodding.)

20 CHIEF JUDGE BUMB: And then from there you then do
21 the but-for world look and say, okay, well, this is what they
22 would have bought.

23 (Witness nodding.)

24 CHIEF JUDGE BUMB: But if the analysis is that there
25 was no value, you still do the but-for world but you start with

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1 zero?

2 THE WITNESS: The -- you still do the but-for world,
3 yes.

4 CHIEF JUDGE BUMB: Yes.

5 THE WITNESS: The difference is, in the but-for
6 world, you pay an amount of money and you get a value for that
7 money that you didn't actually get, and the difference would
8 be --

9 CHIEF JUDGE BUMB: Say that again.

10 THE WITNESS: In the but-for world, you're going to
11 pay some money and so let's say you get the brand, you get
12 Diovan and it's going to treat your hypertension, in that world
13 you get a product that treats your hypertension.

14 Here from the TPPs' perspective, remember they don't
15 actually take the drug, and I am comparing for them these two
16 worlds where they're going to cover the VCDs by manufacturers
17 or something else to see through this particular but-for world
18 whether there's economic evidence of cost savings. So --

19 CHIEF JUDGE BUMB: Yeah. But do the analysis for me,
20 please, assume that they were -- they just were worthless from
21 the beginning, just assume that.

22 THE WITNESS: Yeah.

23 CHIEF JUDGE BUMB: You still do a but-for analysis.

24 THE WITNESS: Yeah.

25 CHIEF JUDGE BUMB: Okay. And walk me through that.

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1 THE WITNESS: Okay. You would still do the but-for
2 analysis. There needs to be the extra step of how do you value
3 the product received. It's got -- how would you value
4 something that actually does manage hypertension compared to a
5 sugar pill. And we actually know that as a matter of
6 economics. We know the value of managing hypertension, because
7 we see the payments for all of these other products that aren't
8 contaminated that do manage hypertension. There's a
9 willingness to pay for products to manage hypertension. That's
10 the value of a product that works.

11 What we don't know is what's the value of the risk.
12 That's the thing that has changed, and it is not part of
13 Dr. Conti's but-for world. So in these analyses I'm
14 considering her but-for world and not a but-for world where
15 okay, well, the difference is the revelation of a risk that
16 wasn't known before. From having reviewed the information,
17 it's my opinion that it's not supported to say the value goes
18 to zero; that we reveal a risk and we wipe out all the value.

19 CHIEF JUDGE BUMB: But I want you to assume it. I
20 want to you assume it now.

21 THE WITNESS: Okay.

22 CHIEF JUDGE BUMB: I want you to assume that they had
23 no value.

24 THE WITNESS: I think if they have no value, then
25 it's appropriate to take away all of the payments for a product

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1 that had zero value.

2 CHIEF JUDGE BUMB: Okay. Because there would be no
3 windfall to the TPPs in that situation?

4 THE WITNESS: There would -- yes, because --

5 CHIEF JUDGE BUMB: Because you can't go back in time
6 and say, hey, pretend like you took the drug ten years ago.

7 THE WITNESS: Yes. They wouldn't -- yeah, exactly,
8 that they would have not managed their hypertension for the
9 last -- yeah.

10 CHIEF JUDGE BUMB: Yeah. Got it. Okay. Thank you.

11 BY MS. BRANCATO:

12 Q. Dr. Stiroh, to do the analysis on slide 23, what kind of
13 data do you look at?

14 A. For slide 23, I looked at an IQVIA dataset that is
15 called -- it's the NSP dataset, and that is tracking prices at
16 the wholesale or manufacturer level.

17 (Court reporter clarification.)

18 BY MS. BRANCATO:

19 Q. I think -- so MSP is the plaintiff. NSP is the dataset.

20 A. Oh, I'm sorry. Yes, NSP. So I have said both.

21 Q. Dr. Stiroh, remind me, what did the IQVIA data show about
22 the alternative ARBs that would have been taken in the but-for
23 world?

24 A. That the price of the alternative ARBs was generally
25 higher in the N, as in Nancy, SP data.

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1 Q. Let's look at slide 24, please.

2 Dr. Stiroh, can you please explain this chart for us
3 and what we see here?

4 A. Yes, I can. I've kind of jumped ahead to this analysis in
5 an answer earlier.

6 So one of the things that I look at is in a TPP
7 dataset, I looked at the actual amount that the TPP called
8 SummaCare spent on patients that were covered by
9 valsartan-containing drugs in the days leading up to the recall
10 and then how much did they spend after the recall. And it's
11 essentially, again, validating this is the outcome. They are
12 not economically better off. Once we get past the recall,
13 they're not economically better off when the products are taken
14 away.

15 So it's the difference in daily spend. So you
16 imagine a patient gets a 30-day supply of valsartan, there's
17 the recall, they get something else, and I can see in the data
18 what else they got, and then I can see how much did the TPPs
19 spend. And the daily spend was about three times higher after
20 the recall than it had been before the recall.

21 CHIEF JUDGE BUMB: Can we go back to your prior
22 slide?

23 You are relying on the IQVIA data. Do you rely on
24 that in the course of rendering opinions?

25 THE WITNESS: Yes, for specific purposes. So one of

1 the things that I think is known where researchers rely on the
2 IQVIA data is for relative prices and price trends. And I know
3 there will be some testimony that I think you'll hear next week
4 about when it gets to a specific price, whether that is
5 accurate. But there are researchers that have looked at, well,
6 do prices come down when generics enter. They use the NSP
7 data, and I'm using that same data to show the phenomenon
8 happens with valsartan-containing drugs.

9 So I think about it as one higher than the next, than
10 the next. That is true. Whether at 322 and then 281 is
11 precisely the right number, that I think is questionable.

12 BY MS. BRANCATO:

13 Q. Dr. Stiroh, going back to slide 24, am I understanding the
14 chart right that based on the TPPs' own claims data produced in
15 this case, you saw cost increases of three times higher after
16 the recall; is that right?

17 A. Yes.

18 Q. And how does the fact that the TPPs' costs incurred after
19 the recall were higher impact what would have happened in the
20 but-for or counterfactual world?

21 A. It is another piece of economic evidence that I look at in
22 evaluating the reasonableness of the damage methodology to see
23 if giving back all of the money makes the plaintiffs whole. In
24 a world where you had taken away the supply of
25 valsartan-containing drugs, the economic outlays, that's the

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1 amount that they would spend, would actually be higher. From
2 an economic sense, the TPPs are not better off in that world.

3 Q. And if the TPP members had switched to less expensive or
4 cheaper alternative drugs, would you have seen that in their
5 claims data?

6 A. Yes.

7 Q. And did you see that in what you saw, in what you looked
8 at?

9 A. Not on average. There's, I mean, different outcomes for
10 different individuals and I'm summing up. So in general,
11 overall, that the cost was three times higher. There may be
12 individuals where the cost was lower, but overall for the whole
13 dataset, the cost was three times higher.

14 Q. Turn to slide 25, please.

15 I want to wrap up today by talking about the key
16 takeaways from your testimony.

17 Can you please explain to us what the first takeaway
18 is?

19 A. Sure.

20 So generally, my understanding of what's being
21 challenged is my consideration of the but-for world analysis.
22 And in my view, that's an economically sound approach to assess
23 the reasonableness of Dr. Conti's opinions, and that was part
24 of my assignment in this case.

25 Q. And the second takeaway from today?

1 A. The world that I'm looking at where this testimony applies
2 is the world where we imagine the taking away of a supply and
3 what else happens in that world. It's different from
4 considering was there some additional cost because they had to
5 pay for a prescription twice.

6 Q. And the world in which you're considering is the same one
7 that Dr. Conti considers; is that right?

8 A. It is the same one with the exception that you'll see in
9 the third bullet that I think hers is incomplete. But it
10 doesn't have assumptions that are consistent with economic
11 principles. If you take away the supply of a product, the
12 price for the remaining product is going to be higher. Or if
13 you switch to an alternative, the price was higher. And that I
14 think was a consideration missing from Dr. Conti's analysis.

15 Q. And the final takeaway for us, please.

16 A. The -- in this but-for world, there is not an economic
17 loss to TPPs where the economic loss is the difference in the
18 payments that they would have made.

19 There has been no showing that there is a difference
20 in financial outcomes for the third-party payors. That's the
21 same as saying that there's not an economic loss or economic
22 injury.

23 CHIEF JUDGE BUMB: As long as there was value?

24 THE WITNESS: As long as there was value, yes.

25 BY MS. BRANCATO:

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1 Q. Dr. Stiroh, under the analysis or the critique you've done
2 of Dr. Conti's damages opinion, do you think that there would
3 be a windfall if the TPPs were awarded damages in this case?

4 A. Yes.

5 MS. BRANCATO: Thank you.

6 Thank you, Your Honor. No further questions right
7 now.

8 CHIEF JUDGE BUMB: Cross.

9 MR. STANOCH: Yes. Thanks.

10 CROSS-EXAMINATION

11 BY MR. STANOCH:

12 Q. Good morning, Dr. Stiroh.

13 A. Good morning.

14 Q. I've David Stanoch. I'll be asking you the questions this
15 morning.

16 I want to go back to the slides. We were just
17 looking at your last slide here, right? TPPs were not injured
18 because they saved money by purchasing at-issue VCDs. Do you
19 have that? You with me, right?

20 A. Yes.

21 Q. So you're saying that TPPs were better off with the
22 presence of adulterated valsartan drugs in the market?

23 A. I am not. I am saying there is no appropriate measure of
24 economic loss to the TPPs in this case. The analysis that was
25 put forward makes them better off than they would have been if

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1 those drugs had never been supplied, when in reality, if you
2 take away -- what economics tells you -- if you take away
3 supply, then the payments by TPPs would have been higher.

4 Q. Well, we'll get back to the takeaway supply, because you
5 said that a number of times, right, as what you think Dr. Conti
6 did, right? That's not what she did, is it?

7 A. I showed the chart from her report. I heard her testify
8 yesterday. I have read her reports. She has taken away -- in
9 her but-for world, she has taken away supply of the
10 valsartan-containing drugs.

11 CHIEF JUDGE BUMB: She didn't even consider it
12 though, did she?

13 THE WITNESS: I'm not --

14 CHIEF JUDGE BUMB: She didn't even consider that
15 there was an alternative supply, did she?

16 THE WITNESS: There I don't know what she considered.
17 She doesn't put forward an analysis of what happens. But the
18 side-by-side charts that I showed where she's got supply and
19 demand in the actual world and then the but-for world, she's
20 taken away supply. She's taking away that supply curve.

21 CHIEF JUDGE BUMB: Right.

22 THE WITNESS: So then I'm then analyzing what happens
23 when you take away that supply curve.

24 BY MR. STANOCHE:

25 Q. And, again, in terms of you saying the TPPs were not

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1 injured and saved money, right, this graph of yours, right --

2 CHIEF JUDGE BUMB: Page number.

3 MR. STANOCH: I'm sorry, page 24, right.

4 BY MR. STANOCH:

5 Q. This is you saying that TPPs, right, spent less money for
6 contaminated drugs than they did once the contaminated drugs
7 were known, right?

8 A. It is factually true. It's not me saying that. I looked
9 at the data from SummaCare. SummaCare spent less on a daily
10 basis prior to the recall than it spent after the recall.

11 Q. Uh-huh. Right. So you're saying they're better off. The
12 TPPs are better off because they're able to buy what you say
13 are low-cost contaminated adulterated drugs?

14 A. That from the TPPs' perspective, the amount of money that
15 they spent would not be lower in the but-for world. So my
16 opinion, there is no economic showing that they would be better
17 off in a financial sense. I'm looking at economic losses,
18 economic outcomes. There is no showing that the economics to
19 TPPs would be better but for the recall. And I consider a
20 variety of things, including the amount that they actually
21 spent post recall.

22 Q. The Judge asked you earlier to assume a world in which a
23 drug product is in fact worthless. Do you recall that from a
24 few minutes ago?

25 A. I do.

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1 Q. And if worthless drugs are sold, I believe you said then
2 the value would be zero, right?

3 A. If a worthless drug -- it's a tautology, but, yes, a
4 worthless drug has value zero.

5 Q. So the tautology of the Judge's hypothetical nonetheless
6 is zero.

7 But isn't it true that if worthless drugs are sold
8 for any period of time, Doctor, the prices paid for those drugs
9 would be a windfall to the manufacturers who sold them?

10 A. In that situation, if the drug is worthless and the
11 hypertension is not being managed, there are other outcomes
12 that could occur, and the approach, the but-for approach is
13 still applicable where you would consider what are those
14 economic outcomes.

15 So imagine the covered patients don't have their
16 hypertension controlled and they have more heart attacks, the
17 TPP has to cover those. The cost to the TPP could be different
18 in one world to the other world.

19 That was not part of the consideration that Dr. Conti
20 did, so I'm considering for the testimony today in that
21 particular vein.

22 In the world at large, if the product was worthless
23 and for six, eight years hypertension hasn't been managed, the
24 economic impact on the TPPs would include are they having to
25 have different economic outlays because of health outcomes for

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1 their patients that would not have occurred had their
2 hypertension been managed.

3 Q. Well, now you're getting a little into your diminution of
4 value opinion. But before we move on to that, Doctor, and I'm
5 happy to, so the takeaway from my question was that in the
6 event worthless drugs are sold for any period of time, the
7 prices paid on those would be a windfall to the manufacturers,
8 correct?

9 A. I don't think you've said it quite correctly. It's got
10 the -- part of the opinion is that there is some value, there's
11 a therapeutic value, and I keep repeating that because there is
12 testimony on that. The therapeutic value and getting the money
13 back, that's where the windfall comes in.

14 If you took away the therapeutic value, then you
15 would also have to think how do you replace that therapeutic
16 value.

17 Q. Well, let's take that first step.

18 You don't -- you said at the very beginning, I
19 believe, you didn't calculate or quantify the value for the
20 drugs actually received by the TPPs' insureds, right?

21 A. I'm not sure what I said specifically. I was asked did I
22 do a calculation of damages that is different from Dr. Conti's,
23 and I did not.

24 Q. Right, you did not. Exactly.

25 And you've testified before at deposition that you

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1 define economic loss as the difference between the price paid
2 and the value received, correct?

3 A. Yes.

4 Q. Right.

5 And so in that sense what you're doing is you're
6 comparing the prices paid for the valsartan on the one hand,
7 right? Yes?

8 A. Well, I need the whole of it. I was nodding.

9 Q. Well, that's part one.

10 A. Okay.

11 Q. Is you need the prices paid for the valsartan that's at
12 issue, right?

13 A. Okay.

14 Q. You agree?

15 A. I'm not sure. Sorry. I'm not -- I don't mean to argue on
16 this.

17 Q. I'm not trying to trip you up, Doctor.

18 A. Okay.

19 Q. So what you need -- your own definition of economic loss
20 is the difference between the prices paid and the value
21 received, right?

22 A. Yes.

23 Q. So then you need two things in that situation, correct?
24 That's what you're saying.

25 A. At least two things.

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1 Q. Sure.

2 A. You might do an analysis to figure those out, but you need
3 those elements, yes.

4 Q. Right. And those elements, right, the prices paid, that's
5 the actual money paid for the drugs versus what you actually
6 got in fact, correct?

7 A. Yes. The value of what you actually got, yes.

8 Q. Right. And that's really expectation damages, right?
9 That's what we're talking about here?

10 A. It could have a number of different names. I think it
11 could be expectation damages. I'm not sure actually if I as an
12 economist would have the same understanding as you as a lawyer
13 on that.

14 Q. Right. But, I mean, your slides talk about the Reference
15 Manual on Scientific Evidence, Third Edition. And you've cited
16 the portion I saw about the make-whole approach, right? You
17 remember that in your slides?

18 A. I do, yes.

19 Q. Sure.

20 And you know if you turn the page of that same manual
21 that they talk about expectation damages as being, quote, are
22 an amount sufficient to give the plaintiff the same economic
23 value the plaintiff would have received if the defendants had
24 fulfilled the promise or bargain.

25 Do you agree with that?

1 A. I do agree with that, yes.

2 Q. Right.

3 So let's go back then to looking at economic loss as
4 we've already said it is, which is the difference between the
5 price paid and the value received, right?

6 So to find out what value is received, we're talking,
7 right, a drug that was contaminated, adulterated with NDMA,
8 what have you, right, we have to determine what the demand and
9 supply is for that product, correct? What are customers
10 willing to pay and what are suppliers willing to sell that,
11 right?

12 A. You have to determine the willingness to pay for that
13 product; or another way to say that is you would have to value
14 the risk, what would people pay to avoid a risk.

15 Q. Right. Well, what we'd have to determine for the value
16 that was actually received, we'd have to know what was the
17 willingness to pay, at what price point would someone say I
18 want that contaminated valsartan drug, right?

19 A. I think it is a slightly different consideration. That
20 the difference between in your view -- what I think we're
21 talking about is diminution of value.

22 Q. Right.

23 A. Where there's an allegation that the value received was
24 less than the value that was bargained for, and there are
25 economic tools to determine a diminution of value. And I

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1 discuss that in my report. I'm under the impression that
2 that's related to worthlessness and not part of today's
3 hearing. But there are economic tools to value risk, and they
4 were not employed by Dr. Conti in this case.

5 Q. Well, they were not employed by you either, were they,
6 Doctor?

7 A. I point out the economic ways to value risk and note that
8 there are still consumers willing to save money to incorporate
9 a risk. And so it's not an appropriate economic assumption to
10 assume worthlessness because of the revelation of a previously
11 unknown risk. You would have to consider other things, such as
12 the magnitude of the risk to the consumer and what they could
13 do to avoid the risk.

14 Q. Right. And you didn't actually --

15 CHIEF JUDGE BUMB: Unless -- unless the notice was
16 they're all placebos.

17 THE WITNESS: Yes. If there's no value of it at all.
18 So I agree, I'm kind of stepping one step past that
19 understanding that the valsartan actually worked.

20 BY MR. STANOCHE:

21 Q. So, again, willingness to pay is one factor, and then
22 obviously there's the supply side of that, too, right? We have
23 a willingness of a supplier to sell the contaminated drug we're
24 talking about as well we have to determine, right?

25 A. I don't think that is the right concept. You're

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1 considering in the actual world what was the value received.

2 We've got the supply. We see how much was sold. The missing
3 piece is what is the value now to consumers. Was it zero?

4 And so my testimony in my report is that there are
5 economic methods, if that is the approach, there are economic
6 methods to consider that, and it wasn't taken by Dr. Conti.

7 Q. And you didn't do anything to quantify that yourself
8 either?

9 A. That is correct.

10 Q. Right.

11 So assume for me we're in trial, if you will, and
12 assume that there's been a finding of a breach of warranty,
13 however defined, that the TPPs here did not receive the benefit
14 of their bargain for these VCDs, okay?

15 A. I have the assumption in mind.

16 Q. Very good.

17 So what's a jury supposed to do to valuate the
18 quantum of damage that was absorbed by the TPPs? How do they
19 valuate then, oh, they got these pills that had NDMA in them?

20 A. I --

21 Q. From your analysis that you offered here.

22 A. I am not offering that analysis. What I anticipate my
23 testimony would be is that the value -- the measure of damages
24 that Dr. Conti will have by that time testified to is
25 incorrect; that she has not valued the risk. She hasn't

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1 determined a diminution of value. I will explain that there
2 are ways that she could have done that but didn't do. I'm not
3 offering them the alternative, and I don't understand it to be
4 a necessary part of my testimony.

5 Q. Right. So you're asking the jury to speculate then that
6 the value of the VCDs actually received, which is part of the
7 expectation damages measure, is some number between 100 percent
8 and zero, but you offer no quantification whatsoever to help
9 them make that decision?

10 A. I offer them the considerations that matter to evaluate
11 whether Dr. Conti's opinion is reasonable.

12 Q. But your opinion is not going to help the jury put a
13 dollar value on the drugs that were actually received, correct?

14 A. I don't know if that is true or not. I am not going to
15 tell them the diminution of value. I am going to tell them
16 that it is not 100 percent and that there are methods to
17 evaluate it and that they were not performed and the measure
18 that Dr. Conti is offering is incorrect.

19 Q. Right.

20 So nothing you're going to tell the jury based on the
21 opinions we have before us now going back two years is going to
22 help the jury determine how much the VCDs were actually worth?

23 A. I don't think that is true. I am not giving them a
24 different damage number, that is correct. But the testimony
25 that I will give the jury will help them evaluate the

1 reasonableness of Dr. Conti's analysis. And whatever else they
2 consider I think depends on what other testimony is offered in
3 the trial.

4 Q. You don't have any facts, do you, that any purchaser of
5 any kind would have willingly paid money for these contaminated
6 VCDs had they known, correct?

7 A. I do. There is testimony that I refer to, I think it was
8 mentioned yesterday as well, at the time of the recalls, the
9 FDA recommended that patients stay on their VCDs. And there is
10 testimony from the Named Consumer Plaintiffs in this case that
11 they did so. They took the VCDs after the revelation of the
12 recall.

13 Q. Well, you're talking ingestion of a drug, right? That's
14 what you just said.

15 CHIEF JUDGE BUMB: Isn't that what you asked her?

16 MR. STANOCH: I agree, Judge.

17 We're talking -- I asked her about evidence of
18 someone -- about --

19 CHIEF JUDGE BUMB: Any purchasers.

20 MR. STANOCH: -- about willingness to pay and would
21 pay for a contaminated drug, not if they would ingest it. Put
22 that aside, right.

23 BY MR. STANOCH:

24 Q. I'm asking you, do you have any evidence of anyone, TPP,
25 consumer, anyone, who says, yes, I would have paid money for a

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1 contaminated valsartan drug had I known?

2 A. I hear you now.

3 Q. And I apologize if I was unclear.

4 A. I have evidence that they did ingest the drug. So they
5 chose to continue to take it after the information was known.
6 I have other discussion in my report about how you can value
7 risks. And one of the things that I note are studies of
8 American consumers who purchase prescription drugs outside of
9 the U.S., and they do that to save money. Outside of the U.S.,
10 it doesn't have FDA approval. The risks are unknown.

11 There was one study by Kaiser Family Foundation that
12 found tens of millions of adult Americans purchasing
13 prescription drugs outside of the U.S. to save money.

14 Part of that is economic evidence that consumers can
15 value risk and they can determine if there is a risk that they
16 are willing to accept for the right price.

17 So what that tells me, it is not correct to just go
18 from 100 percent to zero. There are tools for evaluating what
19 cost, what risk did this put on consumers, what risk did it put
20 on the TPPs, and what is the cost of that risk.

21 Q. Well, you're talking --

22 CHIEF JUDGE BUMB: So can I ask a similar question
23 that Mr. Stanoch asked?

24 Is there any evidence in the record that you saw that
25 after the recall a patient went to the pharmacy, had the drug

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1 prescribed, and the TPP paid for it?

2 THE WITNESS: I think after the recall it is not
3 prescribed anymore. So I don't think there is that scenario.
4 I do think in the IQVIA data you do see some lingering sales,
5 so that's a bit of a mystery.

6 My understanding is that there was not prescribing
7 after that fact, and it wasn't available through a pharmacy
8 after the recall.

9 CHIEF JUDGE BUMB: Okay.

10 BY MR. STANOCH:

11 Q. And when you're talking about evaluating risk, Doctor,
12 right, that presupposes that the person doing the risk
13 evaluation would in fact be able to buy the drug at the price
14 they think is worth discounting for the risk, right?

15 A. It does not, actually. When you think about valuing the
16 risk or what is the difference between the value received and
17 the price paid, that is essentially an academic exercise. You
18 are considering what was the value received. It's different
19 from did you go out to the store to buy it. It's what is that
20 diminution of value, by how much did a value go down because of
21 the presence of an unknown risk. And that can be valued.

22 Q. You don't have -- strike that.

23 Not a single TPP that you know of reimbursed for a
24 valsartan drug after the revelations of the contamination, to
25 your knowledge, right?

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1 CHIEF JUDGE BUMB: Right. She said they weren't
2 allowed to write prescriptions anymore.

3 MR. STANOCH: Right. Thank you, Judge.

4 CHIEF JUDGE BUMB: That's what she said.

5 BY MR. STANOCH:

6 Q. Correct?

7 A. Yes.

8 Q. Right. And you're not aware of any consumer either,
9 right, because they weren't allowed to write prescriptions,
10 right?

11 A. I'm not sure what the end of your question was. Sorry.

12 Q. That's okay. And you're not aware of any --

13 CHIEF JUDGE BUMB: Consumers don't write
14 prescriptions.

15 MR. STANOCH: I'm sorry, Judge.

16 BY MR. STANOCH:

17 Q. You're not aware of any consumers, right, who paid for a
18 drug that was contaminated knowingly because prescriptions
19 weren't written anymore after the revelations, right?

20 A. Correct, we know of the consumers that took the drugs
21 knowingly.

22 Q. Right.

23 A. But I don't think there was a route by which they could
24 have requested a prescription and had it filled.

25 Q. Exactly. Because we all know, and you heard it probably

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1 yesterday, that no one knowingly sells adulterated drugs in the
2 U.S., right?

3 A. That is my expectation, yes.

4 Q. Right. And I can't walk into the pharmacy and say give me
5 the valsartan, a dollar off for some nitrosamines in it. It
6 just can't happen, right?

7 A. You cannot do that. You could walk into a pharmacy in a
8 different country and buy products that are not FDA approved.

9 Q. Right. And we're -- but this case is about sales in the
10 United States about drugs, whether or not they were FDA
11 approved, right?

12 A. Uh, I don't --

13 Q. Do I have any claim -- withdrawn.

14 Do I have any claim under Canadian law in this case,
15 to your knowledge?

16 A. You're asking me a legal question, and I -- the economics
17 doesn't really have borders that way, the economic principles
18 apply, and so information from different countries is relevant
19 in evaluating economic outcomes.

20 Q. Even for a class that's defined as payments for drugs in
21 the United States?

22 A. I think it matters what's the question you're evaluating.
23 And if the question is, can a diminution of risk be valued,
24 then there could be different ways of valuing that risk; that
25 putting a price on risk, economists do it all the time. It was

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1 not done in Dr. Conti's report. But the information one might
2 look at to do that could come from a wide variety of sources.

3 Q. Let's assume that somebody in your counterfactual world
4 would want to pay a discounted price for a contaminated
5 valsartan drug, right? You with me?

6 A. Yes.

7 Q. Okay. And so even assuming you have consumer or purchaser
8 willingness, you still have to look at the availability of that
9 supply, correct?

10 A. Sorry, so the hypothetical is someone wants to pay less
11 for a valsartan-containing drug and doesn't care if it has
12 contaminants in it?

13 Q. Correct.

14 A. Then my understanding is their only option to do that
15 would be to buy it somewhere outside of the United States.

16 Q. Right. Because you understand that there is no company or
17 firm in the United States who even if a consumer really, really
18 wanted it for some odd reason or a TPP said go ahead, it's the
19 cheapest thing, go ahead, no one was selling a contaminated
20 drug with nitrosamines, right, once it was known?

21 A. The -- my understanding the defendants did not sell it
22 once it was recalled.

23 Q. Right. And did you look at the testimony of ZHP's
24 30(b) (6) witness Eric Gu? Do you recall whether or not you
25 looked at that?

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1 A. Well, many years ago. I'm sorry, I don't recall now.
2 You'll have to remind me.

3 Q. That's fine. Whether you did or didn't, are you aware
4 that the question to him was: "Having looked at those NDMA
5 contamination levels, you would agree that ZHP would never have
6 knowingly sold valsartan with those levels of NDMA impurity,
7 correct?"

8 Answer, the 30(b) (6) witness for ZHP: "If we knew,
9 okay, there is NDMA in the valsartan, you know, ZHP wouldn't
10 sell that. That's why it's also -- as soon as we learned there
11 are NDMA in the valsartan, ZHP recall all the products from the
12 market."

13 Do you recall that testimony?

14 A. I have to say I don't have a recollection of it, but I
15 don't have any reason to dispute you.

16 CHIEF JUDGE BUMB: Excuse me. Do either one of you
17 need a break?

18 Do you need a break, Doctor?

19 THE WITNESS: I'm fine to keep going.

20 CHIEF JUDGE BUMB: Okay. If you do, let me know.

21 Go ahead.

22 BY MR. STANOCHE:

23 Q. So, again, in terms of trying to do a diminution of value
24 and saying how much is the value of the contaminated VCD
25 actually received and paid for by TPPs, right, we'd have to

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1 look at, you know, if there would be an availability of it from
2 suppliers. And we know ZHP, for instance, is saying we never
3 would have sold it, right?

4 A. That hypothetical doesn't make sense to me as an economist
5 to say you cannot value risk because it wouldn't have been
6 sold. The way to value risk is you consider -- a willingness
7 to pay for risk is you consider the consumer's perspective.
8 That's what we're trying to value. What value did they put on
9 it?

10 And in your hypothetical you have a consumer that is
11 willing to take on that risk at a lower price, and we would
12 want to measure what is the price that they would be willing to
13 pay to take on that risk, and I'm telling you there are
14 techniques to do that if the consideration doesn't have a
15 market sale.

16 Q. And so what I think I heard you say is only consumer
17 willingness to pay would be pertinent to you if you had
18 undertaken an analysis to determine how much someone would pay
19 for contaminated valsartan drugs?

20 A. In the hypothetical that you gave me, you had a consumer
21 that was willing to take on the risk and you were then
22 questioning whether they could actually go and buy it. And in
23 that scenario, the willingness to pay of that consumer tells
24 you -- the difference between what they would be willing to pay
25 and what they had to pay not knowing the risk tells you what

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1 the value is or the willingness to pay for risk.

2 Q. Without any regard to the supply?

3 A. Yes, for that analysis, we're looking at the diminution of
4 value from the perspective of the consumer, and we would look
5 at how they would price the risk.

6 Q. And are you aware that at least Defendant ZHP had defined
7 the risk as unacceptable for these contaminated drugs?

8 A. Same answer. You're asking me to remember specific
9 testimony.

10 Q. That's fine. I'd like to show you a recall announcement
11 from ZHP.

12 MR. STANOCH: If I may approach, Judge.

13 CHIEF JUDGE BUMB: Yes.

14 MR. STANOCH: Thank you, Your Honor.

15 BY MR. STANOCH:

16 Q. Tell me when you have a moment to look at that, Doctor.

17 A. Yes, thank you.

18 Q. Are you good to go, Doctor?

19 A. Oh, sorry. Just I --

20 Q. Oh, please, take your time and let me know when you're
21 done.

22 A. I have taken a look at it. I may need to look at it a
23 little more closely to answer your question.

24 Q. No, of course, no. Yes. I just wanted you to have it
25 generally.

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1 Have you seen it before, if you remember?

2 A. I think I have seen notices like this. Whether this one
3 specifically, I don't, but, yes.

4 Q. Very fair. It's a press release from ZHP entities about
5 the recall of their valsartan, right?

6 A. Yes.

7 Q. And you see there there's a table on the first page?

8 A. I see the table, yes.

9 Q. Right. And do you see above it there's some italicized
10 language, right?

11 A. Yes.

12 Q. It begins "the exposure," you see that?

13 A. I do, yeah.

14 Q. Could you read that?

15 A. The italicized portion reads: "The exposure to the
16 impurity N" -- thank you very much.

17 Q. "NDMA" is fine.

18 A. Can I say it? Yes. "NDMA that was detected in valsartan
19 product line presents an unacceptable carcinogenic risk to the
20 intended patient population."

21 I'll continue?

22 Q. Please.

23 A. "To date, Prinston Pharmaceutical, Inc., has not received
24 any reports of adverse events related to this recall."

25 Q. Thank you.

1 So we were talking about a consumer valuing the risk
2 of contaminant valsartan. This is ZHP saying itself that that
3 risk is unacceptable, right?

4 A. That is the word that is in the press release, yes.

5 Q. Right. And, in fact, the risk of selling these valsartan
6 drugs is unacceptable notwithstanding the fact that there might
7 not even have been some adverse event report yet, correct?

8 A. I'm only able to read the words, obviously. But that is
9 what they say.

10 Q. Based on the words, you would agree?

11 A. Yes.

12 Q. Right.

13 So in your but-for world, you'd have to consider a
14 consumer willingness to pay for a contaminated drug which the
15 manufacturers of the drugs themselves have said we would never
16 have sold because it presented an unacceptable risk; is that
17 right?

18 A. No. The consideration is can you value the -- can you
19 price the diminution of value, and that can be done but was not
20 done. And that is a different consideration from the
21 hypothetical that you're putting before me of is it sold in a
22 store.

23 Q. And that was a consideration like we've said a number of
24 times you haven't calculated at all yourself, right?

25 A. I have not calculated that, correct.

1 MR. STANOCH: Judge, I'm happy to keep going, but I
2 might shift focus so if you'd like a break. If not, I'm happy
3 to keep going.

4 CHIEF JUDGE BUMB: Anybody need a break?

5 I'm good.

6 BY MR. STANOCH:

7 Q. You okay, Doctor?

8 A. I'm okay. Thank you.

9 CHIEF JUDGE BUMB: How much longer do you have?

10 MR. STANOCH: We'll move through it.

11 CHIEF JUDGE BUMB: May I ask a clarification? Is
12 this witness being proffered as a witness to rebut Professor
13 Conti, or is this witness also being offered as in the
14 defendants' case?

15 MS. ALLON: Rebuttal, right?

16 MS. BRANCATO: Dr. Stiroh is a rebuttal to Professor
17 Conti, Your Honor.

18 CHIEF JUDGE BUMB: So if Professor Conti's testimony
19 is excluded, she's not a witness?

20 MS. BRANCATO: It depends on which part of
21 Dr. Conti's testimony would be excluded.

22 CHIEF JUDGE BUMB: Oh, okay. Understood.

23 (Discussion was held off the record in open court.)

24 BY MR. STANOCH:

25 Q. Doctor, you also talk about -- we heard about alternative

1 drugs, correct?

2 A. I did, yes.

3 Q. Right. And your takeaway seems to be that oh, well, if
4 they didn't pay for these drugs, the valsartan drugs, they
5 would have paid for something else, right?

6 A. My takeaway is that that is not -- the amount that they
7 paid is not the measure of the economic loss because the
8 economic scenario would be that they would have paid more with
9 the expectation that they get a value, that their patients got
10 a value from the valsartan actually consumed.

11 Q. So you'd look at alternate drugs, even though we've said
12 today earlier that you define economic loss as the difference
13 between the price paid and the value received?

14 A. I do. In the entirety of my report, I consider different
15 things with respect to Dr. Conti's analysis. I consider what
16 was said in the complaint about the loss. My understanding is
17 what the plaintiffs were pursuing was compensatory damages or
18 make-whole damages, damages that put the plaintiff back to the
19 economic position they would have been in but for the
20 wrongdoing. And with that framework, then I look at a variety
21 of things.

22 Q. But you don't know if your, as you call it, make-whole
23 damages are the same as expectation damages, right? You don't
24 know?

25 A. I just don't feel maybe comfortable saying that right now.

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1 I'd want to review what the expectation damages, how they are
2 defined.

3 I think it is in fact the same, but I would rather
4 have something in front of me that explains to what the -- how
5 the Court views expectation damages.

6 Q. Well, how do you view it? You say that you use the
7 approach of make-whole damages, right? Make-whole approach,
8 right?

9 A. I have used a make-whole approach, yes.

10 Q. Right. And you've said it, and you said it puts the
11 person in the same position they would have been, right?

12 A. Yes.

13 Q. Right. But you don't know if that's a different theory
14 than expectation damages, do you?

15 A. As I sit here, I think it is the same, what value did you
16 expect to get and what value did you receive. I'm just not
17 wholly comfortable telling the Court that that is identically
18 the same without reviewing if there is a different legal
19 interpretation.

20 Q. Right. And whatever the legal interpretation is would
21 control, not your take on what make-whole versus expectation
22 damages may mean, right?

23 A. My understanding is that, yes, the Court decides
24 ultimately that I can offer my economic opinion of what the
25 economics says and then there are other considerations that

1 come into play.

2 Q. For your alternate drugs theory, you didn't actually --
3 you didn't actually do a full relevant market analysis, did
4 you?

5 A. I did not, correct.

6 Q. Right. Because usually when you're looking at different
7 drugs that are considered substitutes, right, you would have to
8 look at -- you would do a full market analysis of looking at
9 the product and geographic dimensions of a market, correct?

10 A. I disagree with that. You would look at a relevant
11 market, typically in a competition matter, an antitrust matter.

12 Q. Uh-huh.

13 A. Where you're considering is there a price increase for a
14 market, you would need to define that market.

15 Q. Right.

16 A. Now, one of the steps in defining the market is looking at
17 substitutes.

18 In this case I have direct evidence as to what those
19 substitutes are because SummaCare produced data showing what
20 the patients, a patient taking valsartan prior to the recall,
21 what they were switched to after the recall. I can see what
22 those substitutes are. And that's why in the slides there was
23 a slide that said 79 percent switched to another ARB, and so I
24 looked at the prices of ARBs.

25 Q. Well, you agree that defining a market by reference to a

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1 customer of one is not appropriate, right?

2 A. Sorry, by reference?

3 Q. To a customer of one, right? You said you looked at
4 SummaCare, right?

5 A. Oh.

6 Q. Right? A single purchaser is not a market, right?

7 A. I agree, a single purchaser is not a market. The single
8 purchaser is a plaintiff in this case, and they were the only
9 one that produced that sort of data. So I looked at all of the
10 produced data in this case that allowed me to do that analysis.
11 But I also understand, I mean if the class has been certified,
12 it's essentially diminishing differences between class members.
13 But, yes, I agree with you, SummaCare is one of the class
14 members.

15 Q. Right.

16 And to look at products that are reasonably
17 interchangeable substitutes, right, you'd have to consider what
18 products are out there, right?

19 A. I -- from your phrasing, I think you're asking me if you
20 did a relevant market analysis, which I agree I did not do in
21 this case. I looked at for SummaCare what did their patients
22 actually switch to and what were the costs of those
23 alternatives.

24 Q. Right. So you didn't actually do any analysis to decide
25 what drugs are substitutes for valsartan?

1 A. I don't think that's true. I did an analysis to see what
2 drugs were substituted for valsartan. And it sounds like
3 you're asking me didn't I layer on some hypotheticals of what
4 could have been taken.

5 I do consider what could have been taken, other blood
6 pressure-managing drugs, including vitamin C. There are things
7 that you can take that are in the wide world of potential
8 alternatives. In my analysis, I look at what actually was
9 taken.

10 Q. Uh-huh. Right. You didn't actually get pricing data from
11 IQVIA, for example, to look at how much vitamin C was during
12 the relevant time period, right?

13 A. I did not. That analysis doesn't play a role in the
14 calculations that I'm doing. It is more relevant what happened
15 within a TPP, what did their covered patients actually do, and
16 so I looked at that data.

17 Q. And you didn't look at a number of other drugs that are
18 approved to treat high blood pressure. You didn't look at the
19 national sales data for that either, right?

20 A. Again, no. I looked at what was in the SummaCare data.
21 SummaCare produced information on valsartan -- on, sorry, ARBs
22 and other blood pressure medications, and I looked at what
23 patients were switched to and what the costs were.

24 Q. Right.

25 And then in your chart here on slide 20, right, you

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1 look at -- well, you're using IQVIA data here, NSP data?

2 A. Yes. I am looking at NSP data on slide 20.

3 Q. Right. So you're relying on IQVIA data for, you know, at
4 least for this graph of yours, right?

5 A. To evaluate whether pricing patterns for valsartan are
6 consistent with pricing patterns observed by other researchers.
7 I am using the NSP data that's similar to the data that other
8 researchers used to look at that same question.

9 Q. Right. And you've looked at IQVIA data before. We talked
10 about that earlier, I think, right?

11 A. I have, yes.

12 Q. Right. And you understand that defendants themselves in
13 this case have looked at IQVIA data for a variety of purposes,
14 right?

15 A. You're testing my memory there. I don't remember specific
16 testimony about that.

17 Q. Are you aware that ZHP testified that they use IQVIA data
18 for sales and marketing trends?

19 A. I don't have a basis to question whether that's right or
20 wrong. I just don't remember what was said in depositions.

21 Q. Sure. Are you aware that Teva used IQVIA data during the
22 relevant time period to report sales of valsartan in the U.S.
23 market?

24 A. I -- I just don't know the answer one way or the other.

25 Q. Sure.

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1 We'll go back to this chart here on page 20, right.

2 So basically your point here is that the price drops
3 when more product is available in the market, right?

4 A. On slide 20, that is not true. It's the price dropping as
5 more generics enter the market.

6 Q. And you cut this chart off at December 2015, don't you?

7 A. I do, yes.

8 Q. Right. So don't you think it would be important for a
9 jury to know what would have happened in the real world after
10 2015, including after the recalls?

11 A. That depends on the question. I don't know what data I
12 have after the recalls. I'm not remembering from what else is
13 in the analysis.

14 Q. And you're trying to imply here that TPPs actually paid
15 less because there was the contaminated drugs on the market in
16 2014 and 2015, right?

17 A. I'm not at all trying to imply that.

18 Q. No?

19 A. I am showing the economic outcome of generic competition,
20 which I think is a pretty well-established fact. More generic
21 competition generally reduces price. And other researchers
22 have shown that for other products that the more generics there
23 are for a drug indication, the lower the price. And I am
24 saying same thing happens to valsartan using the same data
25 source that other academic researchers use.

1 Q. Right. And the number of entrants, though, you have cuts
2 off at 2015, right?

3 A. Yes.

4 Q. Right. So in a but-for world what you say is if the
5 valsartan from these defendants was not in the market,
6 shouldn't we also look at what happened in the real world after
7 the FDA learned about the contamination?

8 A. I did look at that. I did not use IQVIA data to look at
9 that. I used the claims data produced by plaintiffs to look at
10 that.

11 Q. Well, are you aware that the FDA approved more generic
12 valsartan in the immediate wake of the recalls?

13 A. I don't have those facts in front of me right now. The
14 general fact and what I'm doing this analysis for is to show
15 the price comes down with generic competition. The expectation
16 is that if there is less supply and fewer manufacturers, fewer
17 price invoices, the expectation is the price would go up. I
18 look at a variety of things.

19 But to analyze what actually happened to prices, I'm
20 looking at for the TPPs that have produced data what happened
21 to their actual costs.

22 Q. Right. Well, the point though is, Doctor, that if the FDA
23 approved another five valsartan drugs in the immediate wake of
24 the recalls, right, in a but-for world where the supply was
25 removed for these defendants, those approvals probably would

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1 have happened sooner, right?

2 A. I don't know the answer to that. If there is a generic
3 manufacturer that could enter, I think it's an inquiry, why
4 didn't they enter sooner.

5 Q. Uh-huh. Well, that would be something we'd have to kind
6 of tease out a little bit, huh?

7 A. I disagree. I think it depends on what the question is
8 that you're trying to answer. And if you're evaluating whether
9 the recognized phenomenon of more generic competition leading
10 to lower prices holds for valsartan. The analysis that I did
11 shows that.

12 Q. In terms of alternative drugs that are more expensive,
13 right, on slide 23; you there?

14 A. I have it, yes.

15 Q. Great. So you're only looking at other sartan drugs here,
16 right?

17 A. On slide 23, that is correct, yes.

18 Q. Right. And you're not looking at the other how many dozen
19 of other drugs were approved to treat hypertension, right?

20 A. On slide 23, that is correct. You'll note it follows the
21 slide where I showed that for the TPP data that was produced,
22 the claims data, you can see in the claims data that 79 percent
23 switched to another ARB. And so that is the relevant
24 population that I'm looking at then for slide 23.

25 Q. You're showing here you're trying to say that certain

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1 sartan drugs cost more, right?

2 A. I am showing, yes, that alternative drugs, other sartans
3 had higher prices than VCDs.

4 Q. Well, if in the but-for world you're constructing that
5 somebody would have bought another drug, would it be important
6 to know whether any of these prices were artificially inflated?

7 A. If your theory is that in a but-for world the prices would
8 have been lower, that could be part of the analysis. I am
9 considering for my analysis whether Dr. Conti's damages are
10 supported. And part of that consideration is, is there any
11 support for an assumption that they would have been
12 economically better off in a but-for world where we have taken
13 away supply of valsartan-containing drugs.

14 If you were doing a different analysis of imagining
15 that there would have been different entry or different
16 products available, that is not what is being represented on my
17 slide.

18 Q. Right. If we wanted to really get at the validity of all
19 these numbers for all these different drugs, we would have to
20 explain to the jury at trial whether or not these drugs were
21 the appropriate substitutes. We'd have to explain whether
22 these prices were artificially inflated or not, such as by a
23 U.S. Department of Justice price-fixing investigation that
24 covers some of these drugs. We'd have to look at all the other
25 factors that may be affecting the prices of these other drugs

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1 out there, wouldn't we?

2 A. I don't think you would, for the analysis that we're
3 talking about today. These are the facts that the other drugs
4 in 2012 through 2018 had the prices that they had. So consider
5 if the supply of valsartan were not available, what happens
6 next, not rewrite all of history.

7 The way that you do a but-for analysis, you take away
8 the wrongful act that's being challenged in this case and
9 consider whether there is a route by which economic outcomes
10 would have been better for the TPPs. And through this
11 analysis, I am seeing in the IQVIA data the prices of other
12 sartans were higher. I'm seeing in the MSP claims data that
13 patients were switched to other sartans, and I see the outcomes
14 that payments were higher for TPPs.

15 Q. And you said a number of times Dr. Conti is assuming to
16 take the supply out of the market. Isn't she really positing
17 the value, though, of the drugs that were actually purchased
18 that were received by the TPPs?

19 CHIEF JUDGE BUMB: That they were worthless?

20 MR. STANOCH: Yes.

21 CHIEF JUDGE BUMB: Yeah. That's what she's
22 rebutting.

23 MR. STANOCH: Right. But nowhere does Doctor -- the
24 point, Judge, is, and I may have asked it inartfully, nowhere
25 is Dr. Conti positing a but-for alternative world where the

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1 supply was unavailable. She's looking at the products that
2 were received in real life.

3 CHIEF JUDGE BUMB: Right.

4 MR. STANOCH: She's not --

5 CHIEF JUDGE BUMB: This witness --

6 MR. STANOCH: And Dr. Stiroh, I thought -- I could be
7 wrong, you can correct me, either of you -- said a number of
8 times earlier, right, that Dr. Conti's assuming that these
9 defendants would not have had their supply of drugs in the
10 market, right? And I'm saying that's not something that
11 Dr. Conti does. She's looking --

12 CHIEF JUDGE BUMB: That's right. And that's one of
13 the criticisms this witness has.

14 MR. STANOCH: Right. As long as we're clear on that,
15 that's fine. If you're clear on that, Judge, we're clear.

16 CHIEF JUDGE BUMB: Correct, right? Am I correct?

17 THE WITNESS: Yes.

18 BY MR. STANOCH:

19 Q. And you're offering no opinion about payments TPPs may
20 have received from Medicaid, Medicare, CMS or the federal
21 government, correct?

22 A. In what regard am I offering no opinions there?

23 Q. Well, are you opining -- tell me, are you offering any
24 opinions about payments made to TPPs from Medicaid, Medicare,
25 CMS and the federal government?

1 A. I have Medicare and non-Medicare patients in my analysis
2 of the amounts paid post recall by SummaCare. They are
3 included in that analysis.

4 Q. Other than that, you're not offering any opinions that
5 that money should be some sort of offset to the damages that
6 are being alleged, right?

7 A. I'm not offering those opinions. To the extent that there
8 is a statement made that it's not an offset but it is
9 economically rational, I may have opinions on that, but I
10 cannot recall as I sit here what Dr. Conti has said on that
11 topic.

12 Q. Well, I'm just talking about you, and I'm not trying to
13 play games, Doctor. You had said at your last deposition, the
14 question was: "And you offer no opinion about payments made to
15 TPPs from Medicaid, Medicare, CMS, the federal government,
16 correct?

17 "Answer: I believe that's correct."

18 A. I'll stay with that answer.

19 MR. STANOCH: A moment, Your Honor.

20 CHIEF JUDGE BUMB: Yes.

21 BY MR. STANOCH:

22 Q. Doctor, anywhere in your reports did you quantify the cost
23 of any non-sartan replacement drugs that you say would have
24 been prescribed but for the conduct at issue?

25 A. I quantify the cost of other blood pressure medications

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1 that are in the SummaCare claims data. As I sit here, that's
2 the only place that I can think of that I've got an analysis of
3 those payments.

4 Q. Right. But other than seeing what SummaCare may have paid
5 post recall for a different drug, you didn't look at how much
6 other replacement drugs would have cost during the pre-recall
7 period, did you?

8 A. I don't think I have a chart of those -- of other -- other
9 than sartans, other blood pressure medications. That's
10 correct.

11 Q. And to recap, Doctor, do you have any evidence that a TPP
12 would be willing to pay any amount of money for a contaminated
13 drug?

14 CHIEF JUDGE BUMB: Knowingly?

15 MR. STANOCH: Knowingly.

16 THE WITNESS: I have heard the testimony from
17 yesterday and what you have read to me today, and that's my
18 understanding, that there would not be knowingly -- knowing
19 payments for contaminated drugs.

20 BY MR. STANOCH:

21 Q. And in fact, a TPP could not pay any amount of money for a
22 contaminated drug knowingly because that would be illegal,
23 right? Correct?

24 A. That's a legal determination, not an economic --

25 MS. BRANCATO: Your Honor.

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1 MR. STANOCH: I can rephrase. Wrap up. I can
2 rephrase and wrap up.

3 CHIEF JUDGE BUMB: Well, we're a little far afield of
4 702.

5 BY MR. STANOCH:

6 Q. And a TPP, Dr. Stiroh, cannot pay any amount of money for
7 a contaminated drug in order to get a lower price; is that
8 right?

9 MS. BRANCATO: Same objection, Your Honor.

10 CHIEF JUDGE BUMB: I'll allow it.

11 THE WITNESS: My understanding is that knowingly
12 those drugs would not be available.

13 CHIEF JUDGE BUMB: I have a question.

14 Could you answer this question: If Professor Conti
15 was instructed to assume they had no value, do you fault her
16 analysis?

17 THE WITNESS: I would fault the assumption and say it
18 is not economically reasonable given the testimony in this
19 case. So I hear your question economists may be asked to make
20 certain assumptions and show if that assumption bears out what
21 the outcomes are. But what we have seen in this case is that
22 there is still therapeutic value. And I thought that is not
23 being challenged so I would say it's not a valid assumption.

24 CHIEF JUDGE BUMB: Understood.

25 MR. STANOCH: And, Judge, it's been said a number of

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1 times by the witness and opposing counsel.

2 CHIEF JUDGE BUMB: Yes.

3 MR. STANOCH: And I think our papers will speak for
4 itself that we are challenging the but-for worlds that
5 Dr. Stiroh posits, both the diminution of value and alternate
6 product, drug, right?

7 CHIEF JUDGE BUMB: Okay.

8 MR. STANOCH: I'm not going to belabor it, you have
9 the papers and you can see it, but if you read past the
10 sentence that the defendants talked about yesterday, in our
11 reply brief we're very clear that we are challenging both the
12 but-for world of Dr. Stiroh that someone -- that there's any
13 facts supporting the proposition that someone would willingly
14 pay knowingly for a contaminated drug and if they could do
15 that, because there's no facts supporting that.

16 CHIEF JUDGE BUMB: Right. But why are we going into
17 that? We are not in that. That's just not the record of the
18 case. Those are just hypotheticals that don't really apply to
19 this case. Why are we going down that road?

20 There's not going to be any evidence that the TPPs
21 knowingly paid for these contaminated drugs or drugs that they
22 knew to be contaminated, right?

23 MR. STANOCH: That --

24 CHIEF JUDGE BUMB: So why are we going down that
25 road?

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1 MR. STANOCH: We're going down that road because
2 we're talking about when you're doing -- to determine the
3 value --

4 CHIEF JUDGE BUMB: Are you done with this witness?

5 MR. STANOCH: I think, yes.

6 MR. SLATER: Wait.

7 CHIEF JUDGE BUMB: Okay.

8 MR. STANOCH: Or no, no, I'm not. Two questions.

9 CHIEF JUDGE BUMB: Okay.

10 (Counsel conferring.)

11 BY MR. STANOCH:

12 Q. And I think you agreed earlier, Doctor, but you can
13 correct me if I'm wrong, that you agree that firms cannot sell
14 adulterated valsartan in the market, correct, U.S. market?

15 A. I don't think that's for me to agree or disagree. Again,
16 I think that's a legal question. My understanding from the
17 testimony --

18 CHIEF JUDGE BUMB: You can agree.

19 THE WITNESS: Okay. I'll agree. Thank you. I'm
20 informed.

21 BY MR. STANOCH:

22 Q. And do you agree that there's no legitimate supply curve
23 for contaminant valsartan?

24 CHIEF JUDGE BUMB: You can agree.

25 THE WITNESS: I can agree.

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1 CHIEF JUDGE BUMB: You just can't hold either of
2 those answers against her because I told her to say that.

3 | (Laughter.)

4 MR. STANOCH: Worry about that later. I think I'm
5 good now with the witness, Judge.

6 CHIEF JUDGE BUMB: Okay.

7 MR. STANOCHE: We'll answer some of your questions.

8 CHIEF JUDGE BUMB: No. We're going to have a
9 conversation, but let's finish with the witness.

MR. STANOCH: Okay. Yeah. Thank you.

11 MS. BRANCATO: Just a few follow-up questions, Your
12 Honor.

13 CHIEF JUDGE BUMB: Yeah.

REDIRECT EXAMINATION

15 BY MS. BRANCATO:

16 Q. Dr. Stiroh, I just want to be clear for the record, does
17 Dr. Conti use a but-for world in reaching her damages
18 conclusions?

19 A. She does.

20 Q. And what does that but-for world that Dr. Conti uses
21 assume about supply for VCDs?

22 A. She imagines a world with no supply from defendant
23 manufacturers

24 Q. And does your analysis start with that same but-for world
25 and build on top of that to critique Dr. Conti's conclusions?

1 A. For what I discussed here today, yes.

2 MS. BRANCATO: Thank you, Dr. Stiroh, and Your Honor.

3 No further questions.

4 CHIEF JUDGE BUMB: You can step down. Thank you.

5 THE WITNESS: Thank you.

6 (Witness left the stand.)

7 CHIEF JUDGE BUMB: Let's take a five-minute break and
8 then I have some questions. You all know that Judge Vanaskie
9 is coming back at 1:30 to meet with him.

10 MR. STANOCH: 1:30, yes, Your Honor.

11 CHIEF JUDGE BUMB: So don't go away when we're done.
12 All right. Let's just take a five-minute break.

13 (Recess was taken at 11:22 a.m. until 11:31 a.m.)

14 THE COURTROOM DEPUTY: All rise.

15 CHIEF JUDGE BUMB: Okay. Thank you.

16 You can have a seat.

17 Okay. So I asked this earlier, so Dr. Stiroh is
18 not -- is she just a rebuttal witness to Professor Conti? Help
19 me understand. Because if I exclude the testimony of Professor
20 Conti, do you need a ruling on Dr. Stiroh?

21 MS. ALLON: So with respect --

22 CHIEF JUDGE BUMB: Stiroh. I'm sorry. I forgot how
23 she pronounced it.

24 MS. ALLON: Stiroh.

25 With respect to the opinion that's the subject of the

1 *Daubert*, she is a rebuttal witness to Dr. Conti.

2 CHIEF JUDGE BUMB: Okay.

3 MS. ALLON: Does that answer your question?

4 CHIEF JUDGE BUMB: Oh, I see.

5 MS. ALLON: She has other opinions that aren't being
6 challenged. I just need to think more about --

7 CHIEF JUDGE BUMB: Got it. I understand.

8 MS. ALLON: But I think there may be some of those
9 that are not purely rebuttal.

10 CHIEF JUDGE BUMB: Okay. All right. Do you want to
11 be heard on your motion?

12 MR. STANOCH: Yes, Your Honor. Thank you.

13 Your Honor, Dr. Stiroh said a number of times
14 comments about Dr. Conti's but-for world. Dr. Conti, you
15 didn't hear her say one time yesterday, and you won't see it in
16 her four reports, you won't see it in the five days of
17 deposition transcripts of her saying that she constructed a
18 but-for world of taking the supply out and say, oh, it was
19 never sold. That's not what she does.

20 Dr. Stiroh has a whole bunch of but-for worlds, which
21 we heard about and she goes on and on about, which the net
22 upshot is TPPs made money, they're not harmed, right? That not
23 only was there no harm, there's a windfall to these plaintiffs
24 for buying contaminated drugs that these defendants made
25 millions or more selling that they shouldn't have been able to

1 sell in the first place.

2 Dr. Stiroh -- so I just want to say that Dr. Conti
3 was looking at the benefit-of-the-bargain and the value
4 received and applies the economic principles of how she will
5 tell a jury to do that. So there's no -- this idea that she
6 has another but-for world out there, that's not this case.
7 That's not our theory. They can put forth what they want, but
8 they can't recharacterize our theory.

9 CHIEF JUDGE BUMB: What is your theory?

10 MR. STANOCH: Our theory is that she measures the
11 value of what was, right, the benefit-of-the-bargain, value
12 given --

13 CHIEF JUDGE BUMB: She assumed they had no value.

14 MR. STANOCH: Value given, value received. And she
15 uses economic principles in the literature and the FDA
16 regulatory market to say how she comes to a value of zero for
17 it. We talked about this a lot yesterday. I don't want to
18 retread that. We'll focus on Dr. Stiroh.

19 CHIEF JUDGE BUMB: No. But it's important.

20 Okay. So if her assumption is -- now I'm talking
21 about Professor Conti. If her assumption is not a valid
22 assumption -- and that's what I ruled yesterday, and I'm going
23 to continue to rule, and I'll give some rulings more
24 precisely -- if her assumption is wrong, then her analysis
25 falls. Doesn't it?

1 MR. STANOCH: I don't -- I don't think --

2 CHIEF JUDGE BUMB: Unless, unless I permit the
3 plaintiffs to present testimony, and I don't know what the
4 defense response to this would be, is that she was told to
5 assume.

6 But I asked her that yesterday, I think I asked her
7 that yesterday and she disputed that; that she wasn't told to
8 assume that the value was zero; that she opined that the value
9 was zero. And I don't think that she qualifies under 702 to
10 make that opinion. So that part of her opinion I will exclude.

11 The question is -- and the reason I'll do so, since
12 we're talking about Conti, is that I don't believe that under a
13 702 analysis that her opinion reflects a reliable application
14 of the principles and methods. I don't think that it's a
15 product of reliable principles and methods.

16 When I've reviewed her testimony, I've reviewed her
17 report, what she discusses, and she's an economist, when I
18 reviewed her report she opines such things as that the product
19 at issue must have a zero value. It must be applied because
20 otherwise to do so would be to incentivize and legitimize
21 cheating and noncompliance by manufacturers.

22 That simply is, the way the Court thinks about it is,
23 but that is what the measure of damages addresses. That's what
24 the consumer fraud statutes address.

25 It is not for -- and I don't find that she's

1 qualified to render such an opinion to assess a zero value on
2 that simply because she thinks it's better policy.

3 And she goes on and attempts to bolster her opinion
4 by saying that manufacturers would have no economic incentive
5 otherwise if it weren't the case.

6 So I can go through it more if the parties wish for
7 me to. And, you know, she talks about federal law and how
8 federal law establishes nonsafety and quality compliant and
9 what the federal law establishes, and that they are -- and that
10 they cannot be lawfully sold. That's not disputed here.

11 The question, you know, there is no dispute about
12 that. So I don't find that her opinion with respect to that
13 these drugs had no value, I don't find that it's supported by
14 the data and the reliable application of the principles, and I
15 do not think that it would be helpful to a trier of fact.

16 So having ruled that, the question then becomes:
17 Should I permit her to testify that she was assumed to give a
18 zero value?

19 And the question is: Should I allow that because it
20 seems to me the trial is going to be about did they have any
21 value, and we're going to get to that in a second.

22 My problem is, is when I asked her did she assume it,
23 and she said no. So would I be giving the plaintiffs a second
24 bite at the apple in permitting that testimony? I'll hear from
25 the defendants about what their view is. Or should I permit

1 her to go back and do an analysis with that assumption?

2 But to be very clear, I will not permit her to
3 testify that in her opinion they had zero value, I don't think,
4 under Rule 702. And I've given you my reasons. I'll reserve
5 the right to amend the transcript if ordered or in a
6 supplemental opinion.

7 So having ruled that, what does that mean for
8 Dr. Stiroh, who I found to be eminently qualified, who I found
9 that the principles that she applied were supported by reliable
10 principles and methods, and that she engaged in what I found to
11 be a reliable application of the principles?

12 MR. STANOCH: Well --

13 CHIEF JUDGE BUMB: But is it even relevant at this
14 point if this portion of the testimony that we heard today is
15 strictly to rebut Professor Conti's opinion? It seems not.

16 MR. STANOCH: I think it -- I think it's still a
17 relevant and germane inquiry, Your Honor.

18 CHIEF JUDGE BUMB: It's still a what?

19 MR. STANOCH: It's still a relevant inquiry, I think.
20 I think it's not mooted by what you're suggesting. Just a few
21 things. I just for the record --

22 CHIEF JUDGE BUMB: You preserve your right to appeal.

23 MR. STANOCH: We reserve, yeah, of course. We
24 reserve our rights and understand your ruling.

25 CHIEF JUDGE BUMB: Noted.

1 MR. STANOCH: But reserve our rights on it. And to
2 your other question --

3 MR. DAVIS: Reserve the right to change your opinion
4 as well because, you know, I think you had instructed us to do
5 some briefing on this yesterday. And just this morning I was
6 finding cases where courts allowed under a 702 analysis full
7 refund damages models; for example, the *Fisher-Price Rock 'n*
8 *Play baby toy.*

9 CHIEF JUDGE BUMB: Well, we're going to talk about
10 that, but what I'm precluding is that she is not -- and that's
11 my second question -- that she's not qualified to render that
12 opinion for reasons I've articulated. So it's not a question
13 of whether or not courts allow full refund. That's not the
14 issue. I mean, that's the issue I want the parties to brief.

15 The issue is, is what admissible evidence are the
16 plaintiffs intending to introduce besides Professor Conti's
17 that these drugs were worthless?

18 MR. STANOCH: And I think, again, reserving all of
19 our rights, Your Honor, we understand. But I think Dr. Conti
20 could still testify within the four corners of her reports
21 about obviously the amount of sales during the relevant period,
22 the class period, obviously. I think she can also testify,
23 because she does opine on this in her report, about what
24 happened to the drugs once the revelations became known and the
25 FDA and the price dropped to zero. And I think --

1 CHIEF JUDGE BUMB: And I'm reserving on that part of
2 her opinion, because Ms. Allon has told me or represented to
3 me -- I thought it was she -- that there will be testimony that
4 calls into question her reliance on the IQVIA data. And so I
5 have reserved on that.

6 I'm only ruling on the portion of her testimony that
7 the plaintiffs wish to introduce that the drugs were worthless.

8 MR. STANOCH: Right. And I think the basis --
9 there's one thing where Dr. Conti is saying I think as an
10 economist they're worthless and then showing based on the
11 actual data what happened in the real world as to the value
12 once the revelations were made known. And I think she can do
13 that latter, even --

14 CHIEF JUDGE BUMB: I think she can do that, but I
15 think that's such a small part of the case. I don't think that
16 anyone is really quarreling with, yeah, the sales went down as
17 soon as there was a recall. I don't know that that really adds
18 much to the case, but, you know, it's your case. You'll try it
19 the way you want.

20 MR. STANOCH: Right. And then that would be a way to
21 show the jury to say what happens when the truth is known in
22 terms of the pricing and economic value of the drug, and then
23 Dr. Conti would say that she has aggregated all of the point of
24 sale, POP damages.

25 CHIEF JUDGE BUMB: I'll have to hear the testimony.

1 I'll have to revisit it and see exactly what it is that she
2 would be proffered for. I'm going to reserve on that, yeah.

3 MR. SLATER: Judge, can I --

4 CHIEF JUDGE BUMB: Go ahead.

5 MR. SLATER: -- be heard briefly?

6 Wow, I never stand at these because no one could ever
7 see me.

8 I'm a little concerned. I just would like the chance
9 to talk this out with you a little because obviously it's an
10 important decision.

11 CHIEF JUDGE BUMB: Uh-huh.

12 MR. SLATER: Your Honor stated that you don't find
13 that Dr. Conti is qualified to give the opinion. It would seem
14 to me that she as an economist would be qualified to give
15 opinions on value just as Dr. Stiroh I think you're finding is
16 qualified to give opinions on value.

17 CHIEF JUDGE BUMB: If she assumes that they are
18 worthless, and that's the question, if she assumes that they
19 are worthless. But I asked her yesterday, it was my
20 recollection, are you assuming that these are worthless, she
21 said no --

22 MR. SLATER: Right.

23 CHIEF JUDGE BUMB: -- they are worthless.

24 Now, maybe in fairness to the plaintiffs I should
25 permit her to assume it and maybe perhaps exclude her from

1 opining that they are in fact worthless, because she's not
2 qualified to render that opinion.

3 MR. SLATER: And my concern with that is that it
4 seems to me that the qualification would be she's an economist
5 and she has a background to be able to value pharmaceutical
6 drugs and determine what, if any, value they have and what they
7 would be.

8 CHIEF JUDGE BUMB: Right. But it was such a faulty
9 analysis. Her analysis goes something like this, and I don't
10 want to take up too much time, because if I have to write on
11 it, I will, her analysis was so faulty. Her analysis was:
12 Adulterated drugs have no value.

13 As a general proposition, most people would agree
14 with that if they knew they were adulterated, okay.

15 She is inserting into that that supposition that does
16 not exist in this case. And so, to my understanding, there is
17 no dispute in this case and there's no quarrel that you're
18 getting with your adversaries that defendants, once they knew
19 that they were adulterated, they took them off the market,
20 okay.

21 But for your expert to say that adulterated drugs
22 have no value, they have a value unless it is known that they
23 are contaminated. And that is the critical piece of evidence
24 that she conveniently ignored.

25 She then went on into her policy statements, which

1 really is the role of the FDA and other policymakers. Why does
2 the FDA impose these types of requirements? Why does the FDA
3 impose these compliance requirements? Because we want
4 manufacturers to manufacture noncontaminated drugs.

5 And so we have to send a message to these -- this is
6 what's in her report -- we have to send a message to these
7 manufacturers that you can't do that. And the only way to do
8 that is to ascribe a zero value. That sounds legislative to
9 me.

10 My whole point is, is that I think the analysis was
11 flawed. I can lay it out in a greater opinion if the parties
12 wish.

13 So that's the part that I'm precluding. She cannot
14 opine that they are worthless.

15 MR. SLATER: My concern is that --

16 CHIEF JUDGE BUMB: Yes.

17 MR. SLATER: -- my concern is that Your Honor may be
18 making a little bit of a leap to the idea that she can't give
19 this opinion. I don't think that it was a policy-based
20 opinion. I think that she was saying the reason why you can't
21 sell these drugs, the reason why it's illegal to sell these
22 drugs, there's policy reasons. I don't think that was the
23 grounding of her opinion.

24 I think her opinion was actually -- I think it got
25 lost in the hearing a little bit because there was some

1 questioning that kind of took us off focus. But I think that
2 her opinion was, because as everybody has admitted, there is no
3 legitimate market for contaminated -- adulterated might be
4 pulling us a little bit out of the focus. And I think it sort
5 of confused things a little bit on what's the warranty claim.
6 The bottom line here, the warranty was these drugs are
7 valsartan as approved. I'm simplifying it, but USP drugs.

8 CHIEF JUDGE BUMB: Right.

9 MR. SLATER: They weren't.

10 CHIEF JUDGE BUMB: Okay.

11 MR. SLATER: So the warranty was breached. And
12 that's our theory. That's very straightforward.

13 CHIEF JUDGE BUMB: Okay.

14 MR. SLATER: I don't think you need adulteration to
15 get there.

16 CHIEF JUDGE BUMB: Okay.

17 MR. SLATER: But what Dr. Conti's opinion was, is
18 because there's no legitimate supply curve, and this is an
19 economic methodological issue, I really think that it's not --

20 CHIEF JUDGE BUMB: There's no supply curve when?

21 MR. SLATER: There's no legitimate supply curve ever
22 for contaminated pills that are not the approved pill that was
23 legally approved by the FDA.

24 CHIEF JUDGE BUMB: Okay. But that's --

25 MR. SLATER: And that's a legal concept that nobody

1 can argue with. And I think as an economist, her methodology
2 is absolutely sound, because she took that principle and said,
3 look, as admitted by the defendants, there is no legitimate
4 supply curve. So as a matter of economics, if you can't sell
5 it, there's no value to it.

6 CHIEF JUDGE BUMB: But her opinion has to be helpful
7 to the jurors. Her opinion has to be reliably sound and apply
8 to the facts of the case.

9 What you are asking your expert to do is to rewrite
10 the history of this case. You are asking the jury to assume
11 the defendants knew from day one or day two or day five.

12 Now, if the evidence is at some point they knew, okay
13 then. But that's not what she's saying.

14 MR. SLATER: Well, I think that, and this was
15 something we talked about briefly yesterday, we are not asking,
16 and I don't think we need to ask or even establish the
17 defendants knew. As we talked about yesterday in the
18 regulatory framework that applies here, knowledge is not
19 necessary. What's necessary is that they didn't do the risk
20 assessment that would have gotten them the knowledge. And
21 that's what the FDA --

22 CHIEF JUDGE BUMB: Right.

23 MR. SLATER: -- stopped them from selling drugs for
24 three or four years into the U.S. for.

25 CHIEF JUDGE BUMB: Right.

1 MR. SLATER: So knowledge is not an element of the
2 claims or the regulatory acts. And I think that's kind of
3 tying us up. And I thought about this last night, because I
4 think it's clear Your Honor is concerned about the materiality
5 of the warranty breach and making sure that it's material
6 enough that it could matter enough that there could be a
7 recovery. That was my feeling of maybe what was going on. And
8 I think that you were in that place July 23rd, and I think that
9 was the right place when Your Honor said the unacceptable risk,
10 because that's the regulatory law that's applying, that's the
11 regulatory rules, that is the key.

12 And as Your Honor heard today, and I can tell you the
13 language in that press release was mandated by the FDA. That's
14 the testimony from the 30(b) (6) witness. The FDA made ZHP say
15 in that press release that it had to be recalled because of the
16 unacceptable carcinogenic risk. That unacceptable carcinogenic
17 risk existed from day one whether ZHP knew about it or not.
18 And --

19 CHIEF JUDGE BUMB: But I think you're ignoring the
20 record. And I think that to present that in a vacuum will
21 confuse the jury. I think it will mislead the jury.

22 Yes, contaminated drugs should not have a marketable
23 value because the evidence will be undisputed that no
24 manufacturer -- no pharmacy will buy them. No one will use
25 them --

1 MR. SLATER: It's illegal.

2 CHIEF JUDGE BUMB: -- once they're contaminated
3 because it's illegal.

4 MR. SLATER: It's against the law.

5 CHIEF JUDGE BUMB: Okay. But that ignores the facts
6 of this case.

7 They were sold here. They were ingested. They did
8 have a therapeutic value. And on what basis does Professor
9 Conti say they had no value? She's not qualified to render
10 that opinion.

11 MR. SLATER: I think that -- I'm sorry. I didn't
12 mean to interrupt.

13 MR. HONIK: Adam, just --

14 MR. SLATER: Can I -- I need to finish talking,
15 Ruben, please.

16 MR. HONIK: Go ahead.

17 MR. SLATER: Please. And I'm sorry, I didn't want to
18 interrupt you.

19 CHIEF JUDGE BUMB: Go ahead. The point is --

20 MR. SLATER: Oh, what I was going to say is this,
21 Judge.

22 CHIEF JUDGE BUMB: Go ahead.

23 MR. SLATER: Yesterday I accepted that Your Honor has
24 framed a jury issue on whether or not the therapeutic value
25 actually takes it from zero to some number. And that is -- so

1 we're not saying at this point, understanding where Your Honor
2 is, that it's worthless and they can't argue that there was
3 value. We understand that's never going to happen in this
4 courtroom. So your concern, Your Honor, I think the leap
5 you're making is that you're making the decision that because
6 they sold it and you're making the assumption they didn't know
7 whereas we have evidence they knew, and how far that goes back
8 is something the jury is going to decide. It wouldn't be for
9 us to decide. So there may have been knowledge from day one
10 according to the jury.

11 There's definitely a violation of the risk assessment
12 obligation, which is they should have known, to the extent
13 knowledge is a concern for Your Honor. But it's not -- the
14 fact that they sold it is not a problem for Dr. Conti's
15 analysis. She's looking at it and saying they sold it, but it
16 was a product which was not deemed legally sold because it
17 was -- we know it was contaminated, and the defendants agree,
18 we couldn't sell it if -- we weren't supposed to knowingly sell
19 it. In fact, they said it would be unethical to knowingly
20 sell. So we have all that evidence. So the fact that they
21 sold it can't be the basis on which to exclude the opinion.

22 Dr. Conti's contending with the fact that they sold
23 it and saying what they sold based on economic principles
24 actually did not have value because you're not allowed to sell
25 that product legally.

1 CHIEF JUDGE BUMB: But had she opined something along
2 the lines of should have been rendered worthless. But whether
3 or not they had a therapeutic value is a jury question. Had
4 she framed it in that way, that may have been a permissible
5 opinion. But you are asking to have her say to the jury that
6 they have absolutely no value and they're worthless, when there
7 was no recall.

8 Unless you're going to tie up somehow that the
9 defendants knowingly sold, and on that basis I may revisit it,
10 but if they knowingly sold drugs they knew to be contaminated,
11 then does she then come forward and say knowingly selling
12 contaminated drugs are worthless?

13 MR. SLATER: Well --

14 CHIEF JUDGE BUMB: Because it's just -- she --
15 it's --

16 MR. SLATER: I --

17 CHIEF JUDGE BUMB: Go ahead.

18 MR. SLATER: I think -- I'm sorry, Judge. I think
19 what we're doing is we're mixing liability with a damages
20 model. And I think that that's not what we should be doing.

21 The knowledge component of whether or not they knew
22 does not go to whether or not value was received.

23 CHIEF JUDGE BUMB: But that's why --

24 MR. SLATER: And she can be cross-examined on that.

25 CHIEF JUDGE BUMB: But that's why I asked her, I said

1 are you assuming they are worthless.

2 MR. SLATER: I thought the answer was better and more
3 acceptable to the Court when she said no, what I did was I
4 assumed that they were not -- that they were adulterated. She
5 assumed they were adulterated which the FDA found, so that's a
6 sound assumption. Your Honor has left it for the jury to
7 decide whether they met the definition of adulteration from day
8 one. We --

9 CHIEF JUDGE BUMB: She never -- unless I'm wrong, I
10 don't recall her saying I will assume that they are
11 adulterated.

12 MR. SLATER: She drew that assumption very clearly,
13 Your Honor.

14 CHIEF JUDGE BUMB: To my way of thinking, I'll hear
15 from the defendants, to my way of thinking, there is a material
16 distinction to say to the jury I assumed they were worthless
17 versus they were worthless.

18 MR. SLATER: What --

19 CHIEF JUDGE BUMB: Because they weren't worthless at
20 the time. That's what the evidence will show, the jury will
21 decide, because no one knew of this contaminant.

22 MR. SLATER: Well, your Coach bag example was
23 actually the perfect example to show that it was worthless.
24 And the fact is, as a matter of law, if you sell something
25 illegally, the jury --

1 CHIEF JUDGE BUMB: Now we're --

2 MR. SLATER: It's for the jury. I think where you
3 were before yesterday was it's going to be a jury question to
4 take what Dr. Conti says and to take -- this is an adulterated
5 drug. That was the basis of her opinion. She assumed it was
6 adulterated and then said based on that, adulterated drugs have
7 no value because they can't legally be sold in the United
8 States, and there's no legitimate supply curve for those. End
9 of -- I mean, that is a legitimate methodology. She's
10 certainly qualified to give that opinion.

11 CHIEF JUDGE BUMB: It just has no application to the
12 facts in this case. That's my issue. It has no application to
13 the facts in this case.

14 MR. SLATER: Well --

15 CHIEF JUDGE BUMB: Because there is no quarrel that
16 you will get from the defendants that contaminated drugs cannot
17 be sold, okay.

18 And so for the plaintiffs to come forward and pretend
19 as if they couldn't have been sold back then, if they knew then
20 what they know now injects speculation, conjecture, and isn't
21 what the record will reflect. And that's the concern I have,
22 is that we are injecting -- we are asking the jury to pretend
23 that what happened here didn't really happen.

24 MR. SLATER: I don't --

25 CHIEF JUDGE BUMB: Pretend the FDA recalled it five

1 years ago.

2 MR. SLATER: We're not saying that, though, Your
3 Honor.

4 CHIEF JUDGE BUMB: I don't know. That's how I see
5 it.

6 MR. SLATER: I can assure you, we're not saying
7 pretend -- we're saying this is what happened. And that's sort
8 of what happened today where Dr. Stiroh was saying, well, she
9 has a but-for world. She really doesn't. She's saying in this
10 world you sold these for those -- for that period of time. I
11 don't believe that for her damages model that the knowledge of
12 the defendant matters. What matters is whether she thinks
13 there's a value or not. It's a liability question whether
14 knowledge matters. And it doesn't. We know it doesn't. So
15 we're mixing the two things.

16 And certainly Dr. Conti -- because I know you're
17 wondering if you stay where you are, which I'm hoping I could
18 convince you to not and to let her give the opinion because I
19 think it's very valid -- she certainly can give the opinion
20 there's no legitimate economic supply curve for drugs that are
21 adulterated.

22 CHIEF JUDGE BUMB: But nobody disputes that. That's
23 what I'm trying to --

24 MR. SLATER: But if the jury finds --

25 CHIEF JUDGE BUMB: That is just not disputed.

1 MR. SLATER: But if the jury finds, which we're going
2 to ask the jury to find, that from day one the drugs met the
3 definition of adulteration, it was just later when the FDA
4 found out that they were going to say, oh, yeah, these drugs
5 are adulterated, the conditions that led to the adulteration
6 finding didn't change. It was the same from day one to that
7 point.

8 CHIEF JUDGE BUMB: Okay.

9 MR. SLATER: So if doctor -- so you're going to -- so
10 we already know the jury is going to decide whether -- and
11 maybe that's a question on the verdict sheet -- do you find
12 that they met the definition of adulteration as of for the
13 entire time they were sold? And if they say that, the jury
14 says that, then Dr. Conti's assumption has been proven out by
15 the jury, and then the jury could consider whether or not she's
16 correct.

17 And she certainly could give the opinion -- even if
18 Your Honor says she can't give the ultimate opinion they were
19 worthless, she certainly could give the economic analysis of
20 there's no legitimate market for that. Value is determined by
21 the supply and demand curve, and here's the numbers if you find
22 that there was -- if you, the jury, find the value was zero,
23 here's the numbers.

24 CHIEF JUDGE BUMB: And on that ground, I will review
25 the transcript.

1 Okay. Everyone is standing up. Yes, quickly.

2 MS. ALLON: Okay. So I want to just address the
3 Court, what's happening with Dr. Stiroh, right? We need to
4 address -- I want to come back to that question.

5 CHIEF JUDGE BUMB: No; her testimony is permissible.
6 I found it to satisfy Rule 702 in its entirety.

7 MS. ALLON: Okay.

8 MS. BROWN: Perfect. And Your Honor --

9 CHIEF JUDGE BUMB: But I don't know that it's going
10 to be useful if I exclude the opinion. That's the only part --

11 MS. BROWN: Yes, Your Honor.

12 MS. ALLON: Okay.

13 MS. BROWN: Correct. Sorry. Go ahead.

14 MS. ALLON: Yeah. I was going to make the point that
15 if she's going to present any numbers, right, then Dr. Stiroh
16 is going to be permitted to respond. If Dr. Conti is going to
17 present any damages numbers to the jury --

18 CHIEF JUDGE BUMB: Yes.

19 MS. ALLON: -- then Dr. Stiroh can respond to that.

20 CHIEF JUDGE BUMB: Yes.

21 MS. BROWN: And, Your Honor, I just rise to sort of
22 echo the totality of Dr. Conti's testimony, which I think the
23 Court hit the nail on the head to say she has come before this
24 Court to offer an opinion, she told the Court yesterday she
25 made an independent determination of worthlessness. And as the

1 Court says, that is based on something that are not the facts
2 of the case. It is based on an assumption that back in 2012,
3 the FDA made a finding that they didn't, that the facts do not
4 support; that there was no testing to test for it; that nobody
5 knew this was there; that the FDA says in their press release:
6 American public, you might be wondering how come we didn't
7 catch this? Because we didn't know, because we couldn't test
8 for it, because nobody knew to look for this.

9 And so I think Your Honor hits the nail on the head
10 to say the problem with this opinion, the 702 problem with the
11 opinion is it will not assist the jury because it's not
12 reliable, because it belies the facts of the case where we have
13 a product that was sold for a period of time where the
14 testimony in this case was that it provided value, therapeutic
15 value.

16 And whether it was an assumption or an independent
17 finding, Your Honor, it doesn't survive 702 either way, because
18 it's not based on the facts of this case. And whether they
19 told her to assume that or whether, as she told the Court
20 yesterday, she made that independent finding, either way, it's
21 not reliable. And the Court is spot on in finding it does not
22 survive *Daubert* or 702.

23 CHIEF JUDGE BUMB: Let me review the transcript.

24 MR. SLATER: Thank you. I assume we shouldn't say
25 much more on this.

1 CHIEF JUDGE BUMB: All right.

2 MR. SLATER: I appreciate it, Your Honor. Thanks for
3 hearing me.

4 MR. HONIK: Your Honor, I merely wanted to add that
5 you wisely asked us for legal briefing.

6 CHIEF JUDGE BUMB: Yeah.

7 MR. HONIK: What I think really at the end of the day
8 may control this. If plaintiffs, as we strongly believe, and
9 I've now seen the better part of a dozen or more cases, are
10 entitled to a full refund theory, which is a legally cognizable
11 theory that we have advanced, an economist is entitled to
12 measure that. And if nothing else, and I think everything
13 Mr. Slater said --

14 CHIEF JUDGE BUMB: And if she assumes -- if she
15 assumes that they were worthless, if she assumes that the Coach
16 bag had no value or the fake coat, whatever. But that's a lot
17 of assumptions. But I, you know, I'm going to reread the
18 transcript. But as it stands now, I'm not going to permit her
19 to opine independently that they had no value. I don't -- I
20 think it distorts -- I think it would confuse the jury, but
21 I'll read the transcript.

22 Here's what I want to say, because, you know, I've
23 gone round and round about this whole damages issue, and I
24 think that the issue of -- I think what it boils down to, and
25 Dr. Stiroh's testimony sort of helped the lightbulb go off, so

1 to speak, that what we're really arguing about is compensatory
2 damages and not punitive or fraud damages.

3 And so I am going to share with you just a treatise
4 that I was reading. And basically what it says, and you all
5 can go look at it, and perhaps this is the source of the
6 confusion, which is there are jurisdictions that support
7 benefit-of-the-bargain and then there are jurisdictions that
8 support out-of-pocket. And the treatise goes on to say that it
9 depends upon the jurisdiction. So then of course I say, oh,
10 now what? Do we have all kinds of, you know, jury charges?

11 Ultimately, it seems that -- what this treatise seems
12 to suggest is that ultimately the ends -- how justice best
13 served by the conduct is what the jurisdictions seem to be
14 motivated by. And that's somewhat what Dr. Stiroh was talking
15 about today, which is, you know, parties just shouldn't be
16 getting windfalls.

17 And so I found this very helpful. And so when you
18 folks respond to me, you know, if the jurisdictions are
19 different, you'll let me know. But it does seem to me that the
20 benefit-of-the-bargain, which says to me that the defendants
21 should be permitted to introduce evidence that the drugs had
22 value, is the right way to go. I haven't veered from that.
23 But --

24 MR. DAVIS: May I speak to that, Your Honor, for a
25 second?

1 CHIEF JUDGE BUMB: Yes.

2 MR. DAVIS: Because this is subject to past briefing,
3 and the defendants themselves have agreed that
4 benefit-of-the-bargain is what applies to all the claims in
5 this case.

6 There are certain jurisdictions that do apply
7 out-of-pocket, but there's no meaningful distinction in this
8 case in the sense that the only difference between those two
9 theories is that under a benefit-of-the-bargain, the plaintiff
10 can in addition to getting the difference between the amount
11 paid and the value received, they can get lost upside damages.
12 And that's not what TPPs are seeking in this case at all.
13 We're merely seeking the difference between amount paid and the
14 value received. And so there is no legal --

15 CHIEF JUDGE BUMB: I thought the TPPs -- I thought in
16 some of your briefing you were seeking a full refund, full
17 stop.

18 MR. DAVIS: Well, we are. But that is the difference
19 between value --

20 CHIEF JUDGE BUMB: And there was no
21 benefit-of-the-bargain.

22 MR. DAVIS: Right. The lost upside potential is,
23 like, say that you had a warranty case and the defendant
24 breached the warranty and that caused not only the plaintiff to
25 suffer a difference for the product but maybe they were going

1 to go use the product to like fulfill their own obligations and
2 lost that opportunity to go do that, like, say it's a piece of
3 heavy machinery or something and they had a contract to go use
4 it. That's what the benefit-of-the-bargain entitlement in
5 addition to out-of-pocket gives you. But that's not what TPPs
6 are seeking here. So there is no meaningful distinction
7 between those two theories of economic loss as applied to this
8 case.

9 MR. OSTFELD: Your Honor, Greg Ostfeld. This is
10 certainly an issue that was briefed at the class certification
11 stage. I would respectfully disagree with Mr. Davis's
12 characterization that there's no dispute that
13 benefit-of-the-bargain is the measure of damages across all
14 jurisdictions and all claims. In fact, attached to the class
15 certification opinion there is a table that lays out a number
16 of the differences that were argued in connection --

17 CHIEF JUDGE BUMB: Where will I find that?

18 MR. OSTFELD: Your Honor, it is the appendices to ECF
19 2261. And, for example, there was briefing on which
20 jurisdictions acknowledge zero value theories of damages and
21 which do not. There was briefing about benefit-of-the-bargain.
22 There was briefing on out-of-pocket.

23 I would agree that plaintiffs have presented only one
24 theory of damages across all states and all theories and all
25 claims. And we have certainly argued that there is variability

1 in state law as to those. And what Judge Kugler found at the
2 class certification stage was those legal variances don't
3 prevent class certification, but he did not find that there was
4 a uniform measure of damages across all jurisdictions. That's
5 an issue that was left for trial. I'm sorry.

6 CHIEF JUDGE BUMB: But what Mr. Davis is saying is
7 that even if it's out-of-pocket versus benefit-of-the-bargain,
8 you get to the same place; that you don't get full
9 out-of-pocket because you then have to subtract from that the
10 value. That's what I heard him to be saying; that there's no
11 real material distinction. I mean, instructing the jury is
12 another issue, but that's how I hear him to be saying.

13 So --

14 MR. OSTFELD: So I think the way we would frame the
15 issue is that there are no out-of-pocket damages here because
16 at least the plaintiffs have put forward no evidence of
17 out-of-pocket costs that were incurred by the TPPs. I think
18 Professor --

19 CHIEF JUDGE BUMB: Well, no.

20 MR. OSTFELD: I'm sorry.

21 CHIEF JUDGE BUMB: Well, no, that's not true.
22 They're arguing, which is what Professor Conti presented --

23 MR. OSTFELD: Right.

24 CHIEF JUDGE BUMB: -- which is we paid for sugar
25 pills, we want all our money back. That's their position.

1 Your position is -- that's how I see out-of-pocket. And your
2 position is, no, they weren't, they were effective. They did
3 what they were supposed to do.

4 And I am not going to prevent the defendants from
5 putting on that evidence, so it does seem to me that you both
6 get to the same place even though it's called something
7 different.

8 MR. OSTFELD: I think through the lens of Professor
9 Conti's opinion, it comes down to a similar evaluation. I do
10 still think there are important legal differences, because
11 there are jurisdictions that have not acknowledged Professor
12 Conti's theory, essentially not acknowledging that there could
13 be a zero value theory of damages. And we can certainly brief
14 this and I think --

15 CHIEF JUDGE BUMB: But really, that can't really be
16 true. Like go with my placebo. That really can't be true.
17 What jurisdiction --

18 MR. DAVIS: It depends on the facts of the case.

19 CHIEF JUDGE BUMB: Yeah. What's your --

20 MR. DAVIS: It's not a hardline law in any
21 jurisdiction.

22 CHIEF JUDGE BUMB: Yeah. I think you're overstating
23 it.

24 MR. OSTFELD: I -- perhaps I've stated it inartfully.
25 But I think what the jurisdictions say is you cannot assume

1 zero value as the result of a --

2 CHIEF JUDGE BUMB: Oh.

3 MR. OSTFELD: They essentially reject the theory that
4 Professor Conti has put forward here, which is an assumption of
5 zero value based on the violation, based on the breach.

6 Essentially a per se or strict liability zero value theory is
7 what they reject.

8 CHIEF JUDGE BUMB: I see. I think we still -- you
9 still get to the same place under both causes -- under both
10 theories, though. So maybe it isn't as -- I mean, instructing
11 the jury is going to be a challenge, but maybe it isn't as
12 significant.

13 Okay. Did you want to say something else?

14 MR. OSTFELD: No, Your Honor.

15 CHIEF JUDGE BUMB: Okay.

16 So you're welcome, if anyone wants to see what I've
17 been reading, you're welcome to.

18 MS. LOCKARD: Would you mind sharing the treatise
19 that you're referencing?

20 CHIEF JUDGE BUMB: I took it back to chambers. Is it
21 on the copies? I had my law clerk make copies.

22 I think it's the Fischer treatise on remedies.

23 MS. LOCKARD: Thank you.

24 CHIEF JUDGE BUMB: Yeah. That would be helpful,
25 wouldn't it?

1 Let me just ask my law clerk.

2 I was warned it was a little outdated, so... but it
3 was something.

4 Okay. When do I see you all next?

5 MR. DAVIS: Your Honor, did you want to address
6 Motion in Limine 16?

7 CHIEF JUDGE BUMB: Which one is that one?

8 MR. DAVIS: That's the alternative drugs motion in
9 limine. I think Your Honor may have ruled on it yesterday, and
10 it --

11 CHIEF JUDGE BUMB: Doesn't that dovetail into
12 everything we were just talking about today?

13 MR. DAVIS: It does. We were scheduled to argue it
14 today. It relates to, among other things, Dr. Stiroh's
15 evaluation of alternative drugs, and that it rewrites the
16 damages analysis in this case.

17 As we've talked about many, many, many times, the
18 analysis looks at what was received versus the value of what
19 was received, not parenthetically or what you would have bought
20 in replacement thereof.

21 CHIEF JUDGE BUMB: James Fischer on remedies, Second
22 Edition.

23 MR. DAVIS: Your observation yesterday that would
24 create a law of no damages is correct. I mean, take
25 Dr. Stiroh's ham sandwich example today, contaminated deli

1 meat. Well, she would say you would have gone and bought a
2 different lunch and you wouldn't be entitled to damages.

3 CHIEF JUDGE BUMB: And that's why I want briefing on
4 it. Because to give you the benefit of my thinking, it just
5 seems to me that the purpose of compensatory damages is to make
6 the party whole. And the purpose of punitive damages or
7 fraud-related damages such as fraud protection acts is to
8 punish or make the party pay for his or her conduct.

9 So it does seem to me that to make the party whole,
10 the jury should look to see in its analysis of damages is had
11 this been -- and the jury has to find it, when did the
12 defendants know, when did the defendants know, and did they
13 conceal it? And if they find that they didn't conceal it, they
14 find that they didn't know, then they engage in a compensatory
15 analysis, which I think is similar to what Dr. Stiroh was
16 saying.

17 If they find that they did know and they concealed
18 it, then those damages, they don't get a reward by looking to,
19 well, you would have had to buy it from a third party anyway.
20 That's where punitives come into. That's where fraud damages
21 come into. And that becomes not relevant in a compensatory
22 analysis. And so the jury is going to be asked, as I see it,
23 the jury is going to be asked to do those separate inquiries,
24 what are the compensatory damages, what are the punitive
25 damages, et cetera.

1 And so that's why this briefing is going to be very
2 helpful to me so that I can figure out in context why any of
3 this matters.

4 MR. DAVIS: Well, we're happy to brief this further,
5 Your Honor.

6 MS. ALLON: Yeah. I mean, I can argue it after the
7 briefing. MIL 16 arguments are duplicative of the 702
8 arguments. The plaintiffs make the same set of arguments in
9 both briefs.

10 CHIEF JUDGE BUMB: Yeah.

11 MS. ALLON: I think Dr. Stiroh in her testimony today
12 outlined a number of situations where under her analysis there
13 would be damages.

14 CHIEF JUDGE BUMB: Right.

15 MS. ALLON: So it's not true that it creates a rule
16 of no damages. But I agree, she also testified that it is
17 purely limited to compensatory damages.

18 CHIEF JUDGE BUMB: Compensatory. And that was very
19 helpful, because it got me to focus in on what I need to be
20 focusing on in how I instruct the jury as to what the damages
21 are.

22 MR. DAVIS: Respectfully, her answer was inconsistent
23 with other opinions she's given in this case. She said that --
24 I think in that example you gave of a placebo, Dr. Stiroh
25 testified that TPPs got a benefit of supplying a drug that was

1 safe and effective. Well, that's contrary to all the opinions
2 she's given in this litigation that their only expectation is
3 to meet -- is to supply a low cost drug, as Ms. Allon said.

4 So I don't think that was a very intellectually
5 honest response.

6 CHIEF JUDGE BUMB: Wait. I'm not following you.
7 What are you saying?

8 MR. DAVIS: You gave Dr. Stiroh the example of a
9 placebo.

10 CHIEF JUDGE BUMB: Yeah.

11 MR. DAVIS: And if her alternative drugs theory would
12 preclude recovery on that. And she said that the TPPs -- I
13 think this was -- I think she struggled with the question for a
14 moment and then she said that the TPPs --

15 CHIEF JUDGE BUMB: It was probably my question she
16 struggled with, but okay.

17 MR. DAVIS: Yeah -- got a benefit from supplying a
18 drug that was safe and effective, and that was the benefit they
19 received, but that's inconsistent with --

20 CHIEF JUDGE BUMB: No. And I asked her about the
21 placebo, and I did it a couple of times because, you know,
22 look, I'm trying to get my head around this; but what her
23 answer was is that in that case, the TPP wouldn't get a
24 windfall because they didn't get anything, there was no benefit
25 to begin with.

1 MS. ALLON: Right. She testified --

2 CHIEF JUDGE BUMB: And they should get the full
3 refund. She didn't use those words, but -- and so that's
4 consistent with what it seems to be the purpose of compensatory
5 is. And so that's why I go round and round about I think that
6 it does become relevant to a jury to make a finding of what
7 value did these drugs have.

8 How you folks -- how you folks prove that I haven't a
9 clue, but it does become relevant.

10 MR. DAVIS: We absolutely agree that's a jury finding
11 as to the value.

12 CHIEF JUDGE BUMB: Yeah.

13 Ms. Allon? Yes?

14 MS. ALLON: Yeah; no, I'm agreeing, Your Honor.

15 CHIEF JUDGE BUMB: Okay. All right. So we'll
16 adjourn. And when are you folks back?

17 THE COURTROOM DEPUTY: Next Tuesday.

18 CHIEF JUDGE BUMB: Next Tuesday.

19 MS. BRANCATO: Tuesday.

20 CHIEF JUDGE BUMB: We'll be together again, yay.

21 You know, I'm just going to go off the record for a
22 second.

23 (Discussion was held off the record in open court.)

24 CHIEF JUDGE BUMB: Okay. Thank you, all.

25 MR. SLATER: Thank you, Your Honor.

1 MS. ALLON: Thank you, Your Honor.

2 MS. BRANCATO: Thank you, Your Honor.

3 MR. STANOCH: Thank you, Judge.

4 THE COURTROOM DEPUTY: All rise.

5 (Proceedings concluded at 12:17 p.m.)

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7 **FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE**
8 - - - - -

9 I certify that the foregoing is a correct transcript
10 from the record of proceedings in the above-entitled matter.

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/S/John J. Kurz, RDR-RMR-CRR-CRC

September 12, 2024

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Court Reporter/Transcriber

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